

Plaintiffs' Memorandum in Opposition to Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims

Ex 46 – Mohr Rep. Excerpts

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**Expert Report on
Role of Distributors in Opioid Marketing**

August 3, 2020

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INTRODUCTION

1. I have been retained as an independent expert witness by counsel for the Plaintiffs Cabell County and the City of Huntington ("Plaintiffs") to offer opinions in the following areas:
 - a. To provide an overview of the function and purpose of distributors in marketing strategy generally.
 - b. To comment on the basic duties and obligations of marketers.
 - c. To provide an overview of the role of the wholesale distributor in the opioid supply chain.
 - d. To assess the role of Distributor Defendants, McKesson Corporation ("McKesson"), Amerisource Bergen Drug Corporation ("Amerisource Bergen") and Cardinal Health, Inc. ("Cardinal") (referred to herein as "Defendants" or "Distributors"), in the growth of the demand for prescription opioids, including through marketing. These large corporations are often referred to as "the Big Three," as they collectively are responsible for roughly 92% of the pharmaceutical distribution market in the United States.¹
 - e. To offer opinions on the integration of the distribution channel for prescription opioids, including the Distributors' line-of-sight into both upstream supply and downstream demand.

My opinions are set forth in this report and are given to a reasonable degree of certainty. The basis for those opinions includes the items cited in this report and the attached Schedules; my knowledge, training, education, and experience in the field of marketing; and my expertise in supply chain management and distribution. I reserve the right to change or add to this Report if additional information becomes available.

QUALIFICATIONS (see CV attached as Schedule 1)

2. My position is Regents Professor of Marketing at the University of Montana. I received my Ph.D. in marketing, with an emphasis in distribution channels, from the University of Wisconsin-Madison in 1989.
3. My academic research over the past 30 years has focused on distribution channel management and strategies; marketing strategies related to development and commercialization of technology and innovation; and most recently, the environmental impacts and responsibilities of business.
4. I teach undergraduate and graduate courses in Marketing Management, Advertising & Promotion, Business-to-Business Marketing, Marketing of Technology & Innovation, Data Analytics & Innovation, Brand Management, and Channels Management.
5. Prior to my Ph.D., I worked at Hewlett-Packard (hp) in Cupertino, CA as an advertising coordinator. My role was to coordinate the distribution channel's marketing efforts with our national brand advertising; the objective was to ensure that hp's presence at the point of purchase in local markets was consistent with our national campaign. I coordinated cooperative advertising (wherein hp provided reimbursement to dealers upon verification of qualified dealer/retailer advertising, funded through an accrual program

¹ HDA, *The Role of Distributors in the US Health Care Industry* (2019) at 3. (Available at <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-hda-role-of-distributors-in-the-us-health-care-industry.pdf>)

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as a percentage of purchase of hp product for their stores' inventory) as well as soft-money campaigns for extra promotional efforts by retailers. I also attended trade shows, which helped to funnel sales leads to our salespeople, who called on dealers and retailers.

6. My dissertation research focused on partnerships and alliances between manufacturers and channel intermediaries. Funded in part by IBM, I explored factors that affect how computer retailers perceived manufacturer's communication strategies in their efforts to coordinate channel member activities. At the time of my dissertation research, IBM had recently introduced its PC (personal computer) and was changing its channel strategy. IBM had historically relied on personal selling to call on enterprise customers, but the introduction of the PC necessitated a new channel of sales through retailers and intermediaries.

7. I published multiple articles on channel structure and management in academic journals (e.g., the *Journal of Marketing*, *Journal of Retailing*), business/practitioner journals (*California Management Review*), and trade press (*Computer Reseller News*, and *Marketing Management*).

8. In my role on various editorial boards for the *Journal of Marketing*, the *Journal of the Academy of Marketing Science*, and others, I peer-reviewed multiple manuscripts on distribution channel issues.

9. In addition to having received the Stern Award, the American Marketing Association's award for the best article in distribution channels, I also served on the selection committee.

10. I also serve as a consultant/expert for the State of Montana and the State of Alaska with respect to pharmaceutical marketing.

METHODOLOGY

11. In forming my opinions, I considered the materials listed on **Schedule 2** to this Report, the publications and texts listed in this Report, as well as my professional experience in marketing and distribution. The opinions expressed in this Report are solely my own and are expressed to a reasonable degree of certainty.

12. I was assisted in the assembly of the evidence tables attached to this Report by three research assistants. I supervised and directed their work.

13. My report reflects the basic standards and strategies of distribution channel structure and management, and its role in marketing and increasing and maintaining demand for products.

14. As Defendants were part of the distribution channel for prescription opioids, which takes place in a "closed system" governed by the Controlled Substances Act (CSA), I was provided with relevant section of the CSA and its implementing regulations, including, 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009) (See Schedule 2).

The CSA was passed in response to a drug abuse problem that President Richard Nixon called a "serious national threat to the personal health and safety of millions of Americans," and he recognized that "[a] national awareness of the gravity of the situation is needed; a new urgency and concentrated national policy are needed at the Federal level to begin to cope with this growing

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menace to the general welfare of the United States.”² The following year, Congress enacted the Controlled Substances Act (CSA) as a part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, which was signed into law and became effective on May 1, 1971.³

The CSA was designed to protect the public health by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration, and, as a condition of maintaining such registration, must take reasonable steps to ensure their registration is not being used as a source of diversion of the controlled substance or harming the public health.⁴

Relevant parts of the CSA are excerpted in Schedule 6 to my Report.⁵ In addition, I have reviewed the Expert Report of David Courtright, specifically his sections regarding the CSA.⁶

COMPENSATION

15. My rates for expert work are \$350/hour for research and writing and \$500/hour for deposition and testimony.

PRIOR TESTIMONY

16. I have not testified as an expert at trial or by deposition in the past four years.

OPINIONS

1. A distributor is a channel intermediary that provides a variety of services (logistics and order fulfillment, marketing and sales, training and service/support, etc.) for upstream manufacturers in meeting the needs and demands of downstream customer accounts.
2. Given their privileged role in connecting upstream suppliers to downstream customers, Distributors have a unique lens on product flows, information and payments, both at the manufacturer and the pharmacy levels. Distributors’ technology and information systems provide an interface that ensures supply is synchronized with demand.
3. Within distribution channels for many products sold through retailers, all of the main participants in the channel, including manufacturers, distributors, and retailers, engage in marketing to sell more products. In the opioid distribution channel, the Distributors participated in an integrated supply chain

² Report by the United States House of Representatives Energy and Commerce Committee, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, December 19, 2018 at 27. (hereinafter “Congressional Report”); citing Aron J. Hall, DVM, MSPH, et al., *Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities*, Vol. 300 No. 22, JAMA, 2613, 2619 (2008) and United States Department of Justice National Drug Intelligence Center Report, *Drug Market Analysis 2008: Appalachia High Intensity Drug Trafficking Area* (2008).

³ *Id.*

⁴ *Id.*; see also Expert Report of David Courtright.

⁵ See Schedule 6.

⁶ Expert Report of David Courtright.

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that collectively increased opioid sales over time through various marketing efforts. This supply chain⁷ had a common goal of growing the demand for opioids.

4. To the extent any of the Defendant Distributors claim they did not participate in marketing opioids, those statements would be false. In fact, the Distributors' marketing strategies are highly sophisticated.

5. Because of the tight channel integration of the various members of the opioid supply chain, it is quite difficult to separate one supply chain member's impact from another in terms of each individual actor's responsibility for growing the opioid market. Rather, all parties worked together in a collective and indivisible effort to expand the market.

6. The Distributors played a significant role in expanding and maintaining the opioid market in numerous ways including:

- Sophisticated cultivation of relationships with pharmacists, through providing value-added services to help them operate their businesses, implementing integrated technology platforms, harnessing data based on those relationships to target opioid marketing efforts based on specific pharmacy's buying habits, and conducting research to understand their buying triggers and barriers.
- Provision of sophisticated marketing services to opioid manufacturers, including selling them access to their pharmacy networks for delivering branded advertising and sales promotions to pharmacists, conducting both qualitative and quantitative research of all key stakeholders in the healthcare supply chain in order to identify barriers and triggers for prescribing and using opioids, performing key functions such as staffing field sales personnel on the manufacturers' behalf, training pharmacists in behavioral coaching to ensure patient compliance/adherence to their opioid prescriptions, and training the pharmaceutical sales force in effective selling strategies. The Distributors also provided consulting services for these manufacturers, both

⁷ When I refer to the "supply chain" for prescription opioids, I am referencing the basic distribution channel that takes the opioid drug from labeler (manufacturers) to distributor to retailers (or in some cases direct from labelers to retailers). I have reviewed the Expert Report of Craig McCann, Ph.D, CFA and the Appendices thereto. The supply chain for the Cabell-Huntington market is generally illustrated by the Vertical Integration of Oxycodone Shipments to Cabell County and the City of Huntington, WV in Total Dosage Units from Labelers to Distributors, Vertical Integration of Oxycodone Shipments to Cabell County and the City of Huntington, WV in Total Dosage Units from Distributors to Dispensers, Vertical Integration of Hydrocodone Shipments to Cabell County and the City of Huntington, WV in Total Dosage Units from Labelers to Distributors, Vertical Integration of Hydrocodone Shipments to Cabell County and the City of Huntington, WV in Total Dosage Units from Distributors to Dispensers tables appended to the Expert Report of Craig McCann at Appendix 10(e). Based on the Expert Report of Craig J. McCann, Ph.D., CFA, I understand that from 2006 to 2014 the three Defendants in this case were primarily engaged in the sale and shipment of semisynthetic opioids, including oxycodone and hydrocodone (herein I will refer to the drugs Defendants' sold and shipped listed in Dr. McCann's report generally as "Defendants' Drugs"). According to Dr. McCann's report, oxycodone and hydrocodone accounted for 85.9% of all dosage units in the transactions in Cabell County and Huntington City, West Virginia from 2006 to 2014 (McCann Report at Appendix 6a).

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creating marketing strategy (e.g., segmentation analysis, value proposition design, etc.) and implementing marketing strategy.

7. Distributors were compensated in two direct ways for the services they provided to the pharmaceutical manufacturers: they were paid on a traditional fee-for-service model (used by most marketing/advertising agencies), and they received a percentage of the sales increase (“lift”) attributable to their specific marketing efforts. (They also received their traditional compensation based on mark-up on product sales, chargebacks, etc.). Hence, the Defendant Distributors were not “neutral” actors having no stake in whether opioid sales went up or down but, instead, were highly motivated/incentivized to increase sales of opioids.

8. Marketing is more than branded advertising designed to create awareness and generate sales of individual branded products. Marketing also includes indirect marketing based on creation of content (continuing education, speaker series, white papers and journal articles) designed to create favorable impressions of credibility and expertise where customers may not be aware of—and therefore less skeptical about—the entity behind the effort. Known as thought leadership and /or content marketing, the Distributors performed these marketing activities for the opioid manufacturers further elevating the opioid demand.

9. Indirect marketing also includes strategies designed to cultivate primary demand and demand for the product class as a whole. For example, the pharmaceutical industry engaged in a concerted effort to change the healthcare industry’s and society’s perceptions of opioids — as well as to influence regulation and legislation — in the United States through front groups (American Pain Foundation) and trade associations (Healthcare Distribution Alliance—the HDA, previously known as the Healthcare Distribution Management Association—the HDMA). The Distributors not only participated in these marketing activities, but also played a leadership role in them.

10. Marketing includes public relations (PR) designed to influence media and cultivate favorable coverage. Through the HDA, the Distributors collectively joined forces to hire communications and advocacy agencies that effectively influenced media to convey their message about opioids and pain management.

11. All these activities successfully enlarged the market for opioids and increased opioid sales.

12. Any company that participates in marketing a product – from manufacturers, to distributors, to retailers – has a duty to do so without causing harm. This is especially true when a company is selling a dangerous product to vulnerable consumers. When that product is a controlled substance subject to the Controlled Substances Act, all who market, sell, or supply the product have a duty to protect the public health and ensure that their marketing or participation in the growth for demand of a product is not injuring the public health.

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DETAILED OPINIONS AND BASIS

I. The Big Three (Defendant) Distributors

The Distributors “are at the heart of the US health care ecosystem,” and claim to “play a critical role in supporting patient safety.”⁸ As of 2017, 92% of all prescription drugs were sold through a distributor, and the business is dominated by three large companies.⁹ “Pharmaceutical distributors’ \$450 billion in annual revenue is highly concentrated among three traditional full-line distributors: AmerisourceBergen, Cardinal Health, and McKesson,” and the combined market share “for these three companies grew from 87 percent in 2013 to 92 percent in 2017.”¹⁰ Between 2002 and 2017, revenue for the Big Three Distributors increased from \$98.5 billion in 2002 to roughly \$450 billion in 2017, an over four-fold increase.¹¹ One of the reasons for the increase in growth for the Big Three Distributors was substantial increase in growth of opioid sales between 2002 and 2011.¹²

As the HDA reports, “In addition to enabling a secure, transparent, and efficient pharmaceutical supply chain that safeguards patient safety, distributors offer value-added services such as independent pharmacy support, generic sourcing programs, hub services, and innovative partnerships.”¹³ The HDA report also highlights how, “beyond operational efficiency,” the distributors also support the efficient flow of information and money,” by, for example, “managing contracts and facilitating chargebacks.”¹⁴

The fact that the Distributors’ role goes beyond transport is also reflected in the general description each company provides to its investors.

Cardinal Health is “a global integrated healthcare services and products company providing customized solutions for hospital systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide.”¹⁵ In the United States, Cardinal Health’s pharmaceutical segment “distributes branded and generic pharmaceutical, over-the-counter healthcare and consumer products through its Pharmaceutical Distribution division to retailers (including chain and independent drug stores and pharmacy departments of supermarkets and mass merchandisers), hospitals and other healthcare providers.”¹⁶ Cardinal Health “maintains prime vendor relationships that streamline the purchasing process resulting in greater efficiency and lower costs for [its] customers,” and “provides services to pharmaceutical manufacturers including distribution, inventory management, data reporting, new product launch support and contract pricing and chargeback administration.”¹⁷ In sum, Cardinal

⁸ HDA, *The Role of Distributors in the US Health Care Industry*, at 3.

⁹ *Id.* at 8.

¹⁰ *Id.*

¹¹ *Id.*

¹² IQVIA Institute, *Medicine Use and Spending in the U.S., A Review of 2017 and Outlook to 2022* (2018) at 20-21.

¹³ HDA, *The Role of Distributors in the US Health Care Industry*, at 4.

¹⁴ *Id.* at p.10.

¹⁵ Cardinal Health Form 10-K (2016).

¹⁶ *Id.*

¹⁷ *Id.*

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Health's Pharmaceutical segment "connect[s] patients, providers, payers, pharmacists and manufacturers for integrated care coordination and better patient management."¹⁸

AmerisourceBergen is also a global company having "pharmaceutical sourcing and distribution services" that "help both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."¹⁹ Its "business strategy is focused on the global pharmaceutical supply channel where [it] provide value-added distribution and service solutions to healthcare providers (primarily pharmacies, health systems, medical and dialysis clinics, physicians, and veterinarians) and pharmaceutical manufacturers that increase channel efficiencies and improve patient outcomes."²⁰ AmerisourceBergen distributes brand-name and generic pharmaceuticals "and related services to a wide variety of healthcare providers," and "also provides pharmacy management, staffing and additional consulting services, and supply management software to a variety of retail and institutional healthcare providers."²¹ According to AmerisourceBergen, its drug distribution and related services are "designed to reduce healthcare costs and improve patient outcomes."²² "We work with manufacturers to improve product launches and expand markets."

McKesson is a global company with a US pharmaceutical distribution business that "supplies branded, specialty and generic pharmaceuticals and other healthcare-related products" to "retail national accounts (including national and regional chains, food/drug combinations, mail order pharmacies and mass merchandisers)," "independent retail pharmacies," and "institutional healthcare providers (including hospitals, health systems, integrated delivery networks, clinics and alternate site providers)."²³ McKesson's pharmaceutical distribution business also "provides solutions and services to pharmaceutical manufacturers. This business sources materials and products from a wide array of different suppliers, including certain generic pharmaceutical drugs produced through a contract-manufacturing program."²⁴ Its Manufacturer Marketing partners with pharmaceutical manufacturers, "delivering an unmatched combination of communication, distribution, packaging, and pharmacist-coaching options, plus targeted analytics of exclusive data, designed to enable brands to ... optimize resources and improve profitability."²⁵

Hedly Rees, a consultant specializing in pharmaceutical supply chain management,²⁶ states that "the pharma companies would never be able to get their products to patients without the wholesalers....the net result is that the entire distribution network is in the hands of third parties; none of it is owned by the pharmas, not even the ability to collect cash from customers. That is all embedded in the channel network. Increasingly, pharmas need the wholesaler to get their products to customers and receive cash in return."

¹⁸ *Id.*

¹⁹ AmerisourceBergen Form 10-K (2016).

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ McKesson Form 10-K (2016).

²⁴ *Id.*

²⁵ McKesson, *Manufacturer Marketing Custom Solutions for Driving Brand Performance* (2010).

²⁶ Rees, Hedley, *Supply Chain Management in the Drug Industry* (2011) at 155.

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Given the concentration of purchasing power with the Distributors, Rees further notes that any company that relies on the services of these players is “in a weaker position when it comes to bargaining.” Rees continues: “No one is going to believe even the biggest big pharma company if they said they could achieve it themselves.” This importance of Distributors is echoed by Jack McCain, who states that “failure to construct a good distribution channel for a new specialty pharmaceutical product can result in poor prescriber uptake.”²⁷

II. Marketing Basics²⁸

Although specific industries may have unique characteristics, the scope of marketing strategy generally concerns itself with how a company/organization creates differential advantage (competitive advantage) in the marketplace in which it competes. Marketing requires (a) providing products/services that customers value, (b) pricing them in such a way that signals that value; (c) creating awareness and stimulating demand for those products, and (d) distributing those products where and when customers need them. In addition, marketing concerns itself with providing customer service to ensure loyalty and repeat purchases for long-term profitability.

Marketing strategy guides strategic priorities and resource allocations, and hence, plays a large role in decisions managers make regarding selling products and services. Companies develop marketing strategy based on a systematic process of identifying strengths, weaknesses, opportunities and threats in a marketplace (sometimes referred to as a SWOT analysis); segmenting markets; honing their focus on key target markets; crafting value propositions that resonate with targeted customers; implementing the marketing strategy; and then evaluating the results/return-on-investment of that strategy on an ongoing basis.

Marketing may differentiate between competitors (brand marketing), or it may attempt to expand demand for an entire market (economists refer to this as primary demand, demand for the product class as a whole), a strategy which benefits all sellers. Companies/industries use this broader marketing strategy when there are benefits from collective action (e.g., to address key barriers that all companies face collectively). This form of marketing often relies on industry trade associations to implement. For example, in the pharmaceutical industry, the Healthcare Distributors Alliance (HDA) undertook communications and advocacy work that benefited the Defendant Distributors collectively. These trade associations serve the interests of its members and perform key functions that would be costly or less impactful if individual member performed that function on its own. Among these common functions that trade associations perform are government lobbying, media relations, and other communications and advocacy services. By working behind-the-scenes to influence favorable media coverage and government relations, the industry trade association bolsters the ability of all companies to market and sell their products successfully.

Marketing strategies are based on a nuanced understanding of the market environment into which those products are sold. Market research is a critical component of understanding customers, competitors, and the environment in which companies operate (e.g., the regulatory and socio-cultural

²⁷ McCain, Jack, *Connecting Patients with Specialty Products; Part 1: Distribution Models for biologics and other specialty pharmaceutical products*. Biotechnology Healthcare (Summer 2013) at 8-13.

²⁸ Kotler, Philip and Gary Armstrong, *Principles of Marketing* (17th edition, 2018). Pearson.

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environment). It is the foundation of designing a marketing strategy, in that a targeted strategy is based on the underlying research regarding latent market potential and how to cultivate and realize that potential in the market. In addition, research is used to identify the barriers to increased sales and then to develop marketing strategies to overcome those barriers. Given their sophistication, the Defendant Distributors conducted research to understand each target market's buying motivations and developed strategies to address those motivations.

Marketing strategies are typically multi-faceted and are designed to grow product sales through different channels. Strategic marketing decisions are made in four key areas, comprised of "the 4 Ps:" Product, Price, Place, and Promotion:

- Product refers to the items/services a company offers to customers in the marketplace
- Price is the monetary exchange of value
- Place refers to the places at which customers gain access to a product (also known as the channel of distribution)
- Promotion (sometimes referred to Integrated Marketing Communications) includes the use of advertising, public relations, personal selling, and promotional incentives (rebates, coupons, etc.). Sales promotions are divided into either consumer promotions (targeted to the end users of a product) or trade promotions (targeted to channel members; the word "trade" in marketing refers to "distribution channels").

With respect to Promotion, marketing is premised on a strategy of deepening engagement with a customer during that customer's buying process (sometimes referred to as a customer journey). For example, first, a customer must become aware of a product; then they must understand its key features and benefits; then they must make a decision about whether to purchase the product (which often entails overcoming inertia of habitually buying a different brand or product); and then they evaluate whether the product lives up to expectations or not. Hence, marketing tends to rely on an integrated approach to marketing communications, in which advertising is used first to educate and inform customers about products (e.g., create awareness) before more detailed information is conveyed in the form of flyers, emails, etc. Later, customers may be exposed to incentives to create the impetus to buy, including coupons or rebates that provide a financial motivation to purchase. Depending upon the product, salespeople also play a key role in each of these tasks.

As is seen in the case of the marketing for prescription opioids, marketing can be brand-specific and targeted to key customers, or it can be designed to change or maintain attitudes regarding a class of products (like prescription opioids) or an industry as a whole, and thus sell more products. As illustrated by the marketing of prescription opioids described herein, marketing strategies have become multi-faceted and utilize a broad range of tools far beyond direct marketing (e.g., advertising), including a variety of indirect marketing tools:

- Public relations/stakeholder engagement
- Thought leadership and unbranded (content) marketing
- Media relations
- Government relations

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As was true with opioid industry marketing, often these indirect marketing tools are often NOT associated with any one brand per se, but instead, are designed to indirectly influence customers' and other stakeholders' perceptions of the industry and product category as a whole.

Public relations (PR) refers to efforts by a company to influence the way various stakeholders perceive the reputation of a company or industry. PR is a sophisticated field, and PR professionals use an array of strategies and tactics to cultivate positive perceptions. In the opioid market, the pharmaceutical companies and the Healthcare Distributors Alliance hired specialized PR professionals for communications, media relations, and advocacy work.

Media relations entails proactive outreach to various media outlets (key journalists, publications, etc.) to influence the media coverage given to a company, its products, or an industry.

Part of media relations is known as crisis communications. When a company or its products have created harm in some way, appropriate marketing strategy is to maintain a proactive, strategic response team ready to go into action to mitigate possible damage.

Government relations entails cultivating relationships with key government officials and agencies to influence decisions that affect a company, its products, and industry regulations.

As mentioned previously, PR efforts are sometimes managed by industry trade associations on behalf of its members. This is often a tool used to elevate the market by portraying broad consensus on points that will benefit all industry players.

An increasingly important marketing strategy companies use is referred to as content marketing (aka thought leadership). Via content marketing, a company becomes a 'trusted expert' that customers rely on for advice, insights, and knowledge on relevant topics pertinent to the customers' business/industry. Examples include company blogs, webinars, white papers, email newsletters, and other content whose purpose is not specifically to market a particular branded product, but instead to position the company as a trusted leader about important topics. The common goal is for the audience to turn to their trusted advisor for sales. This tool might include offering educational programs and other information prospective customers would find useful.

Additionally, this "unbranded marketing" includes sponsoring thought leaders, industry groups or associations who serve as influencers for the company's product and initiatives. These more indirect forms of marketing can be an important source of marketing when it is difficult to place traditional ads in front of a particular target market. Moreover, this marketing approach creates credibility in a more subtle fashion, bypassing the usual skepticism customers have with traditional marketing tactics. These indirect tools are particularly important when some of the target customers are professionals, such as doctors or pharmacists, as is the case with prescription opioids.

Continuing education programs are an example of marketing through thought leadership. For-profit companies often offer continuing education programs to satisfy the requirements for different classes of professionals to stay licensed/registered in good standing with their licensing bodies (e.g., continuing legal education for attorneys; continuing professional education for accountants; continuing medical education for healthcare professionals). Because for-profit companies know that their targeted customers (e.g., licensed professionals) are required to complete a certain number of hours of

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continuing education to renew their licensure, they offer their “thought leadership” marketing initiatives as continuing education.

Another example is using expert spokespeople. Marketing often relies on expert spokespeople to harness the credibility and expertise these spokespeople have to indirectly “burnish” their products’ image through a halo (carryover) effect. Using expert spokespeople is obvious when we see it used in advertising. However, when these experts are paid influencers that are not identified as such, the technique is more powerful, because it bypasses the usual skepticism customers (especially professionals) have with traditional marketing tactics.

As is clear in the case of the opioid supply chain, companies that manufacturer a product are not the only entities that market products. In today’s era of integrated supply chains, all companies, from the manufacturer to distributor to retailers, participate in designing and executing a coordinated marketing strategy focused on selling product to end users. For example, Coughlan and Jap stress the importance of manufacturers and channel intermediaries each bringing “the necessary complementary competencies to create explosive channel growth together,” as well as the scale necessary to manage the demand that such explosive growth generates.²⁹

Reliance on technology and data affords a company important visibility into key market trends, and data drives many aspects of the supply chain. In pharmaceutical marketing, given that the majority of pharmaceuticals flow through three companies, the Distributors have unique visibility up and down the supply chain. Indeed, as stated by the HDA:³⁰

- “Visibility into downstream inventory data informs manufacturers’ demand forecasting and production decisions.”
- “Visibility into upstream supply data can help pharmacies gauge continuity of supply and prepare for shortages.”
- “The government also relies primarily upon data provided by the distributors for suspicious order monitoring efforts.”

Technology and data are, therefore, key resources to the various participants in the opioid supply chain. To facilitate data sharing, the opioid manufacturers and Distributors shared information systems (through electronic data interchange, known as EDI, or virtual private networks, known as VPNs). Similarly, Distributors have the opportunity to link with the customers’ (pharmacies’) technology systems, providing just-in-time information for automated order fulfillment, enterprise resource planning (ERP) systems for production, and upstream supply chain management. In fact, Distributors offer and provide a number of data-driven services to pharmacies including: automated pharmacy dispensing, data management services, direct-to-customer order fulfillment, pharmacy management systems and services and prescription data capture.³¹ “Beyond operational efficiency, distributors also support the efficient flow of information and money in the pharmaceutical ecosystem.”³²

²⁹ Coughlan, Anne T. and Sandy D. Jap, *A Field Guide to Channel Strategy: Building Routes to Market*, (2016) at 150. CreateSpace.

³⁰ HDA, *The Role of Distributors in the US Health Care Industry* at 10.

³¹ *Id.* at 13.

³² *Id.* at 10.

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Data is also important in customer relationship marketing (CRM). CRM leverages technology (the internet, software, databases, etc.) and data analytics to develop a database of customers and their purchase history to identify the most important customers (e.g., 20% of customers account for 80% of the volume of sales) and personalize offers to each customer based on his/her personal transaction history and other pertinent knowledge that companies have about the customer (birthdays, credit scores, preferences, etc.). It also allows companies to cross-sell and up-sell other items and services with the idea of increasing the customer's "share of wallet" and lifetime value. The targeting strategies Defendant Distributors used in placing the pharma manufacturers' ads and promotions in front of specific pharmacies based on past purchase volume, purchase of competitors' brands, and products purchased in the past six months are illustrative of their sophisticated CRM use. Additionally, Distributors utilized these customer databases to send targeted promotion on behalf of opioid manufacturers to specific customer segments.

When done well, marketing provides what economists refer to as "utilities" (e.g., sources of value):

- Form utility refers to creating products (e.g., manufacturing) that customers desire;
- Possession utility refers to helping customers take ownership of the products (e.g., by offering credit/financing);
- Time utility refers to making products available when customers want/need them; and
- Place utility refers to making products available where customers need/want them.

The Distributors' marketing focused on facilitating form utility, ensuring possession utility by offering rebates, discounts and pricing incentives to customers, ensuring time utility in ensuring an uninterrupted supply chain, and place utility in making the products accessible and available.

III. Basic Duties of Marketers

Like any professional discipline, any company or person participating in marketing a product must follow a code of conduct in its marketing strategy. Many marketing professionals rely on the code of conduct found in the American Marketing Association's Code of Ethics (see Schedule 3). This code of conduct highlights the responsibility to "do no harm," to foster trust in the marketing system by avoiding deception, and building customer confidence in the integrity of marketing through core values of honesty, responsibility, fairness, respect, transparency, and citizenship. Entities or individuals who do not adhere to this basic duty jeopardize trust in the system and the safety of customers.

In addition, various marketing sub-specialties such as marketing research professionals, digital marketers, salespeople, and competitive intelligence professionals also have additional codes of ethics.

Marketers must be especially careful with respect to public relations. The Code of Ethics for the Public Relations Society of America (see Schedule 4) specifically identifies examples of improper conduct that include industry trade associations or other entities that appear independent but are actually funded and influenced by companies with a vested interest (also known as "front groups"), or recruiting people to participate in ostensible grass roots campaigns (also known as "astroturfing"). In addition, the PRSA's Code of Ethics stresses the importance of avoiding situations where one's professional interests conflict with society's interests. In the case of opioid marketing, these basic duties were violated by Defendant Distributors.

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The Federal Trade Commission also has explicit rules regarding the use of paid spokespeople and other influencers. In its goal to stop deceptive ads, its Endorsement Guidelines provide detail about how advertisers and endorsers can comply with law, stating that “if you work with brands to recommend or endorse products, your endorsement message should make it obvious when you have a relationship (“material connection”) with the brand, including a personal, family, or employment relationship or a financial relationship – such as the brand paying you or giving you free or discounted products or services.” This law is designed to “make the recommendations honest and truthful, and it allows people to weigh the value of your endorsements.”³³

Industries that sell potentially dangerous products have heightened standards of conduct that they must follow. The Code of Practice for the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)³⁴ acknowledges that “Our industry is unlike any other – our products can prolong and save lives. We therefore hold ourselves to higher ethical standards than other industries.” In addition, the Pharmaceutical Research and Manufacturers of America (PhRMA)³⁵ acknowledges, “we are committed to following the highest ethical standards as well as all legal requirements. We are also concerned that our interactions with health care professionals not be perceived as inappropriate by patients or the public at large.” It continues, “[p]romotional materials provided to health care professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications.” “All companies that interact with health care professionals about pharmaceuticals should adopt procedures to assure adherence to this Code.” In the case of opioid marketing, these duties were violated by Defendant Distributors.

Rees notes that pharmaceutical channels have unique requirements: “careful storage, handling, tracking, and commercial accounting of the products so that no unintended harm or damage is done to any and all parties concerned” (p. 87). He continues to say that, because the detailed workings of pharmaceutical channels are extremely complex, “strategies must be devised and implemented based on a detailed understanding of requirements, and critically, patient value must be at the forefront” (p. 87). The World Health Organization publishes guidelines which make clear that: “All parties involved in the distribution of pharmaceutical products have a responsibility to ensure that the quality of pharmaceutical products and the integrity of the distribution chain is maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent.”³⁶

³³ FTC, *Disclosures 101 for Social Media Influencers*, (November 2019). (Available at <https://www.ftc.gov/tips-advice/business-center/guidance/disclosures-101-social-media-influencers>)

³⁴ IFPMA, *New IFPMA Code of Practice* (2019) (Available at <https://www.ifpma.org/subtopics/new-ifpma-code-of-practice-2019/>)

³⁵ PhRMA, *Code on Interactions with Healthcare Professionals* (September 2019) at 2, 6, 13 (Available at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Code-of-Interaction_FINAL21.pdf)

³⁶ World Health Organization. *WHO good distribution practices for pharmaceutical products (Annex 5)*. WHO Technical Report Series, No. 957, 2010. (Available at

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A company that sells potentially harmful products to a vulnerable population (e.g., the elderly or those with lower socio-economic status due to poverty, lower educational attainment, etc.) has an even higher duty in marketing these products.³⁷ West Virginia was unquestionably one of those vulnerable populations, given its issues with poverty, work place injuries and, as the opioid industry began supplying the state with a wave of opioids, severe issues with opioid diversion, addiction, abuse, overdose and death.³⁸

Based on data showing that people identify marketing strategies targeting harmful products to vulnerable populations as unethical, marketers should anticipate adverse market consequences (boycotts, negative word of mouth, etc.) that will negatively impact their firms' reputations.³⁹ Marketers in these situations must tread cautiously, attending thoughtfully and carefully to an elevated duty of care. Defendant Distributors appeared willing to ignore these societal expectations, given that they endured significant negative press as they continued to pursue opioid sales.

Considering these industry standards, continuing to widely market a product when said product is causing a public health epidemic is extremely problematic and fails to comply with the basic standards of care that should apply to all marketers. Ignoring these standards undercuts the responsibility to "do no harm," and undermines customer confidence in the integrity of marketing system.

IV. Marketing and the Practice of Distribution Channels⁴⁰

As noted above, "place" is a critical component of marketing strategy. It refers to decisions a company makes regarding how to distribute its products to various customer market segments. In other words, place decisions reflect the various channels of distribution a company uses to perform key functions, including managing key customer relationships; performing warehousing and logistics services; managing customer fulfillment, ordering, and returns; providing information and services to customers; and cultivating demand. As Coughlan and Jap state:⁴¹

"Ultimately, the goal of any channel strategist is to achieve coordination; this occurs when all members act in harmony so that their joint productivity is maximized. Put differently, the team must win, not just the individual players. Channel coordination can be achieved only through the coherent and collaborative actions of all channel members."

https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS_957Annex5.pdf?ua=1.

³⁷ Smith, N. Craig & Elizabeth Cooper-Martin, *Ethics and Target Marketing: The Role of Product Harm and Consumer Vulnerability*, *Journal of Marketing* (July 1997) at 1-20.

³⁸ United States House of Representatives Energy and Commerce Committee, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia* (December 19, 2018) at 25-26; Ruhm CJ., *Deaths of Despair or Drug Problems?* NBER Working Paper No. 24188 (2017).

³⁹ Smith, N. Craig & Elizabeth Cooper-Martin (1997), "Ethics and Target Marketing: The Role of Product Harm and Consumer Vulnerability," *Journal of Marketing* (July), pp. 1-20.

⁴⁰ Kotler, Philip and Gary Armstrong, *Principles of Marketing*, Chapters 12 and 13; Coughlan, Anne T. and Sandy D. Jap, *A Field Guide to Channel Strategy: Building Routes to Market*.

⁴¹ Coughlan, Anne T. and Sandy D. Jap, *A Field Guide to Channel Strategy: Building Routes to Market* at 91.

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Channels play a key role in providing the “utilities” previously mentioned in the form of place utility (available WHERE a product is needed by customers); time utility (available WHEN a product is needed); possession utility (helping customers take ownership of a product, say, by offering credit and financing arrangements); and form utility (offering the appropriate bundle or assortment/mix of products customers want).

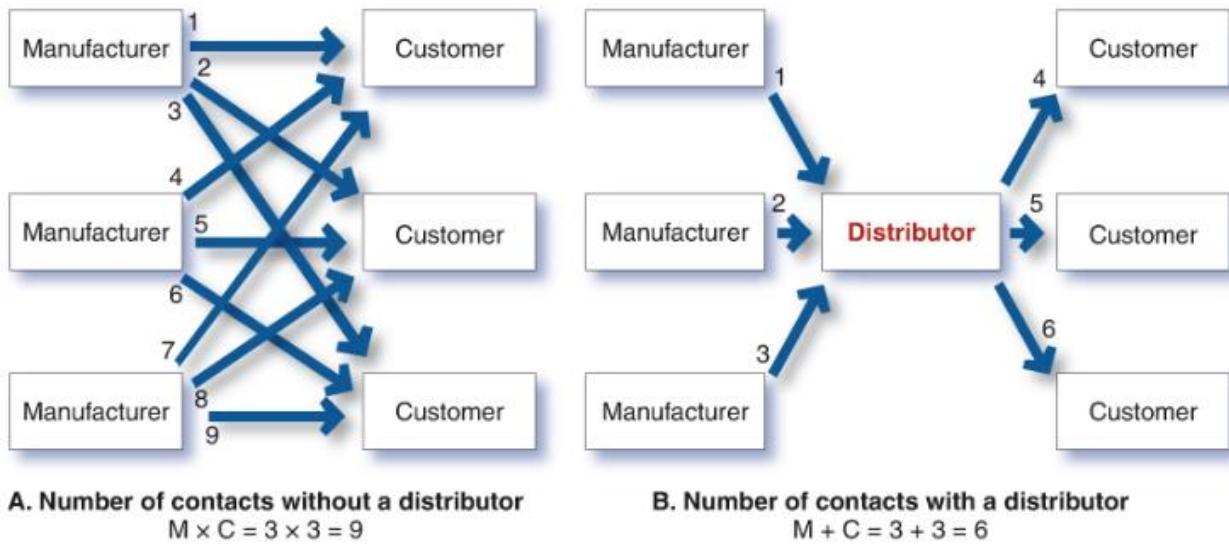
In a high-functioning distribution channel, the parties “function as if they were one.”⁴² Indeed, the independent channel members “may cooperate even better than do the divisions of a single firm.”⁴³ These tight alliances allow channel members to make their own marketing efforts more successful, which translates into higher volume and higher margin.⁴⁴ This is how the distribution channel for prescription opioids worked. Each Distributor closely collaborated with its pharmacy customers (some of whom were part of the company’s pharmacy network). The Distributors also performed strategic marketing activities for the pharmaceutical manufacturers. Their value-added services to both upstream suppliers and downstream customers made them an integral part of the opioid industry’s marketing efforts, and they benefited from their tightly knit relationships.

As shown in the Figure below, in the Distributors’ role linking the opioid manufacturers to their downstream customers, distributors offer “contact efficiencies;” they reduce the number of contacts, or customer interactions that manufacturers would otherwise need to engage in. Without channel intermediaries, each manufacturer would need to set up relationships (e.g., contacts) with each customer in order to conduct business. This “unintermediated” system quickly becomes unwieldy. For example, in a market with three manufacturers and only three customers, the number of transactions needed for each customer to evaluate each manufacturer’s offering would be 3×3 , or 9 transactions. In contrast, by relying on channel intermediaries, the number of contacts (relationships) each manufacturer must establish, and coordinate is sharply reduced. With the distributor acting as the representative of the manufacturer’s product, each manufacturer need engage with only one, or in this case three, distributors, and each customer need engage with only that distributor, leading to an additive model, or $3 + 3$ transactions = 6. This streamlining of touchpoints is the primary reason manufacturers use distributors to most efficiently market their products.

⁴² Coughlan, Anne, Erin Anderson, Louis Stern, and Adel El-Ansary (2001), *Marketing Channels*, Prentice Hall, 6th edition at 316.

⁴³ *Id.*

⁴⁴ *Id.* at 320.



Manufacturers also rely on channel intermediaries to “break bulk,” meaning that distributors buy products in large quantities from the manufacturer, and then perform the service of dividing these large orders into smaller orders to service customers (here pharmacies) on behalf of the manufacturer. This breaking bulk function includes stocking inventory until customers need it.

Channel intermediaries also “create assortments,” meaning that they can assemble a broad product mix from a variety of different manufacturers who offer different products, and then customers gain access to this broad product assortment with a single point of purchase. Therefore, these intermediaries (e.g., the distributors) have the best visibility as to the whole range of manufacturers supplying the market.

Distribution channels serving the pharmaceutical industry exhibit these functions. Rees describes the role wholesale distributors in the pharmaceutical industry play in breaking bulk (take large shipments from manufacturers and break them into the smaller orders that various pharmacists and other retail outlets require) and managing complicated payment issues.⁴⁵ In addition, distributors “reduce the number of transactions that would occur if each retail pharmacy or health care practitioner/center had to order products directly from manufacturers.”⁴⁶

The Figure below shows several options companies may consider in designing channel strategy. First, a direct channel (direct distribution) refers to a company’s reliance on its own resources to market, sell, and distribute to its customers. This can include a company’s own internal sales force, sales through its own .com website, or orders taken via an 800 number or catalog sales. Direct channels are often used by companies that sell primarily to large business customers or companies that market and sell their products direct-to-consumers (DTC).

⁴⁵ Rees, Hedley, *Supply Chain Management in the Drug Industry* (2011) at 87; See also Whewell, Rob, *Supply Chain in the Pharmaceutical Industry: Strategic Influences and Supply Chain Responses* (2010) at 173-174. Routledge.

⁴⁶ See Dabora, Matan, Namrata Turaga, and Kevin Schulman, *Financing and Distribution of Pharmaceuticals in the United States*, JAMA (July 4, 2017) at 21.

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Second, indirect channels refer to channels where companies rely on intermediaries in their channel strategies. Indirect channels include situations where companies rely on retailers such as channel partners. These companies not only market their products directly to the end customer through their own advertising, but also rely on their retailers to market. The Figure also shows that indirect channels also include situations where companies rely on wholesalers to serve retail customers that in turn sell to actual end users.

Most manufacturers use multiple channel strategies, referred to as “multi-channel marketing” to reach various customer segments. However, in the prescription drug market, Distributors handle 92% of pharmaceutical sales.⁴⁷

Specifically, the way opioid pharmaceuticals flowed from opioid manufacturer to distributors to dispensers into Cabell County and the City of Huntington is generally illustrated in the Vertical Integration of Oxycodone Shipments to Cabell County and the City of Huntington, WV in Total Dosage Units from Labelers to Distributors, Vertical Integration of Oxycodone Shipments to Cabell County and the City of Huntington, WV in Total Dosage Units from Distributors to Dispensers, Vertical Integration of Hydrocodone Shipments to Cabell County and the City of Huntington, WV in Total Dosage Units from Labelers to Distributors, Vertical Integration of Hydrocodone Shipments to Cabell County and the City of Huntington, WV in Total Dosage Units from Distributors to Dispensers tables appended to the Expert Report of Craig McCann at Appendix 10(e).⁴⁸ According to Dr. McCann’s report, oxycodone and hydrocodone accounted for 85.9% of all dosage units in the transactions in Cabell County and Huntington City, West Virginia from 2006 to 2014 (McCann Report at Appendix 6a).⁴⁹ Primarily, prescription opioids flowed through the opioid supply chain as illustrated in Option 3 below, with the Distributors performing the vast majority of the wholesaler distribution services in Cabell County and the City of Huntington.⁵⁰

⁴⁷ HDA 2019 report, The Role of Distributors in the US Health Care Industry, at p.3.

⁴⁸ See Expert Report of Craig McCann, Ph.D., CFA at Appendix 10(e).

⁴⁹ *Id.* at Appendix 6(a).

⁵⁰ *Id.* at 10(e).

Levels of a Distribution Channel

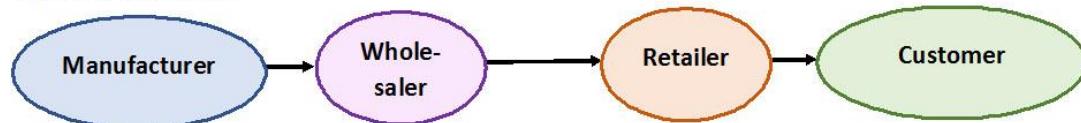
Option 1: Zero Levels (Direct distribution)



Option 2: One Level



Option 3: Two Levels



Because the vast majority of opioid sales flow through the Distributors, it is key (from the manufacturer's perspective) that the distributor is an extension of the manufacturer's own business. This includes not only the manufacturer's mission, values, and culture, but also its ability to seamlessly integrate the product's marketing strategy to maximize product sales. Close collaboration between the manufacturer and distributor on marketing strategy and implementation is critical so that the product's positioning/messaging is conveyed and transmitted to downstream customers with consistency and integrity. Channel members who are not "on message" (or on brand) can damage the manufacturer's marketing investments in brand building and brand equity. As Coughlan and Jap note, channel members perform communication activities designed to increase awareness, educate, and build brand equity, such as advertising, sales promotion, PR, trade shows, etc.⁵¹

Moreover, channel members are key to optimizing a manufacturer's presence with the customers each channel member serves (here, the pharmacies that the Defendant Distributors already serve with respect to numerous other drugs), which by necessity entails coordinating marketing activities. For example, it is vital that the manufacturer's national marketing efforts are reinforced and visible in local/regional markets where customers engage with the various channel members that carry the manufacturer's product. Branding expert Kevin Keller states that intermediary support is critical to maximizing the value of a manufacturer's marketing strategy.⁵²

⁵¹ Coughlan, Anne T. and Sandy D. Jap, *A Field Guide to Channel Strategy: Building Routes to Market* at 59.

⁵² Keller, Kevin Lane (2008), *Strategic Brand Management: Building, Measuring, and Managing Brand Equity*, Prentice Hall, 3rd edition.

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Channel partners, like the Distributors, often hold key relationships with the retail partners who sell directly to the consumer (such as it is here with the pharmacies who made the sale to the end user). Manufacturers that enter a new market or market a new product often capitalize on these established trade partnerships to maximize their product sales as part of their overall marketing strategy.

To assure maximum market penetration, manufacturers, such as the opioid manufacturers here, rely on their distributors to be part of their marketing efforts. To incentivize these marketing efforts, manufacturers offer their channel partners merchandising allowances and other price deals. Manufacturers also offer wholesalers and retailers incentives to stock products and to provide favorable treatment, particularly for new products. The opioid manufacturers gave the Distributors all these incentives.

Moreover, as here, compensation is used to align the channel members' interests with the manufacturers. For example, by compensating intermediaries for increases in sales performance of the manufacturer's brand over time, the manufacturer ensures the intermediary's objectives are compatible with its own.

A well-oiled channel runs like a well-oiled machine, running on all cylinders in synchronicity for optimum performance—for both effectiveness and efficiency—to optimize the manufacturer's presence in the downstream markets channel members serve.

Key to effective channels is the coordination between manufacturers and distributors, which is heavily dependent upon the flow of information. Distributors must know when new products are being introduced, their personnel must be trained on how best to market the new products to their customers, and they must be viewed as key partners in a firm's marketing strategy. This was evident in the opioid industry, given that the Defendant Distributors were viewed as critical to the success of the launch of opioids, and the role the Defendant Distributors played in helping the manufacturers hone their marketing messages.

Similarly, in their role as intermediaries between manufacturers and customers, distributors have access to critical market information including knowledge of market trends, and knowledge of customer behaviors (purchasing patterns, utilization, and customization needs) that is quite valuable. Hence, manufacturers cultivate cooperative relationships to help facilitate the willingness of channel members to share information.

Channel performance can be evaluated on several different metrics. Sales through a channel member (compared to historical sales; sales of other intermediaries; quota; etc.) is a common metric. In addition, satisfaction of customers with the intermediary's service might be used, as might the manufacturer's satisfaction with the intermediary's efforts on its behalf.⁵³

Even as they serve various manufacturers, distributors also have their own business and marketing issues to consider. Each distributor must differentiate its services both to the manufacturers whose products it carries as well as to the customers who choose to buy products from a one distributor vs. another. Coughlan noted the role of value-added services, such as product training. These services allow the distributors to work closely with the manufacturers and helps to build the market for their

⁵³ Kumar, N., Stern, L. W., & Achrol, R. S., *Assessing reseller performance from the perspective of the supplier*. Journal of Marketing Research, 29(2), 238-253 (1992).

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products.⁵⁴ Consequently, the Distributors offered these value-added services to the opioid manufacturers that engaged the Distributors to provide them.

V. Distribution Channels in the Opioid Industry⁵⁵

The distribution channels in the pharmaceutical industry, including the distribution channels for prescription opioids, are highly integrated.⁵⁶ Indeed, all aspects of the channel worked in an integrated system to increase the demand for prescription opioids, maintain that demand, and then ensure the demand is supplied. The most basic way to depict the integrated distribution channels in the pharmaceutical industry is shown in the Figure below. (Unlike the prior figures, this figure places the consumer/patient at the top and the manufacturer at the bottom.) Note that the flow of product is separate from the flow of money/payments/rebates. This basic structure has remained consistent over the years. Indeed, the interconnected nature of the system makes it virtually impossible to place a specific value on each individual actor's contributions to the overall growth of the opioid market in the United States; rather, all played an important role in the coordinated marketing effort in a substantial and meaningful way.⁵⁷

⁵⁴ Coughlan, Anne, Erin Anderson, Louis Stern, and Adel El-Ansary, *Marketing Channels* at 320.

⁵⁵ Rees, Hedley, *Supply Chain Management in the Drug Industry*. 2001. Wiley.

⁵⁶ See evidence presented in Section VI.

⁵⁷ See evidence presented in Section VI.

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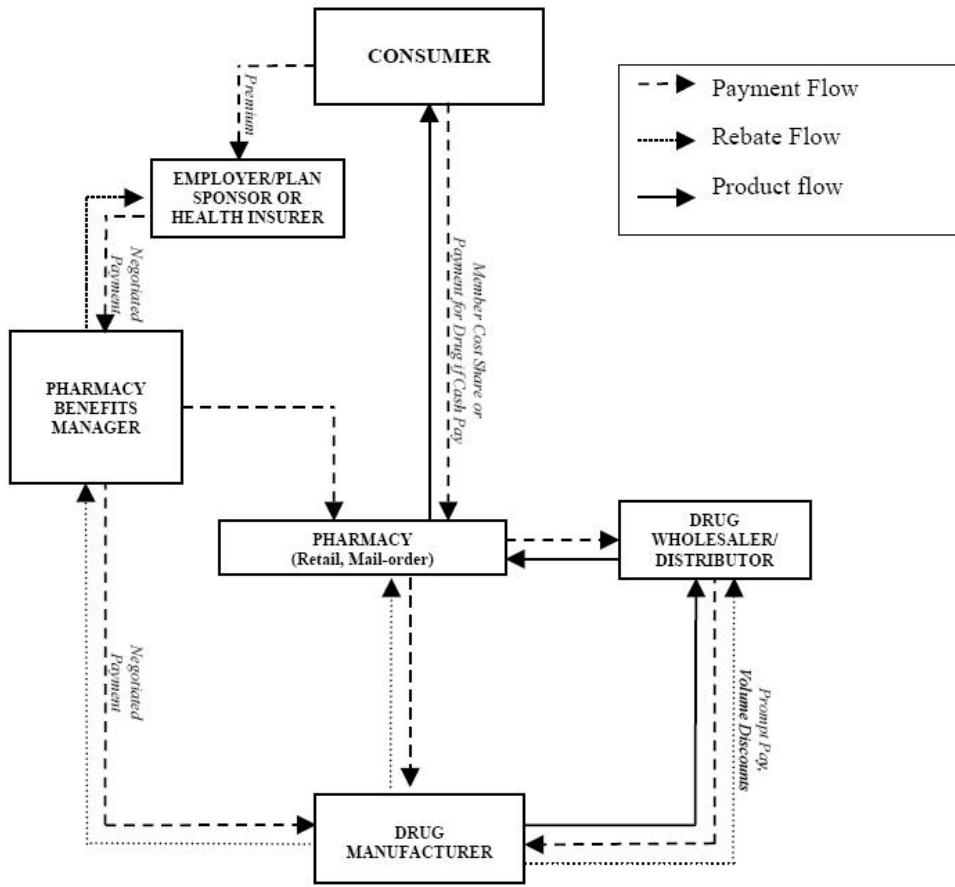


Figure. Major Players in the Pharmaceutical Distribution Channel⁵⁸

The major players and their role in the channel are described as follows:⁵⁹

Manufacturers establish the wholesale acquisition cost (WAC), which is the baseline price for wholesalers to purchase the products; discounts, rebates, and in some cases, fees for marketing services, are deducted from this amount, as explained subsequently.⁶⁰ note the typical financial incentives manufacturers offer pharmaceutical distributors include volume discounts, market share-based bonuses/rebates, and other allowances (e.g., trade promotions to distributors); manufacturers also offered consumer sales promotions (e.g., a coupon for three free pills, or reduced co-pays) to be redeemed at the pharmacist. Drug manufacturers provide incentives to insurance health plans,

⁵⁸ “Follow the Pill: Understanding the U.S. Commercial Supply Chain,” (2005), prepared for the Kaiser Family Foundation by the Health Strategies Consultancy LLC; available at <https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>; downloaded June 29, 2020. See also Rees (2011), p. 87.

⁵⁹ *Id.*

⁶⁰ Rollins, Brent and Matthew Perri (2013), *Pharmaceutical Marketing* (2013) at 117. Jones & Bartlett Learning.

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Pharmacy Benefit Managers, and distributors. I elaborate on the services distributors provide to manufacturers below.

Wholesale distributors sell to pharmacies at the WAC plus a desired margin; these distributors also facilitate negotiation of discounts between manufacturers and other players in the industry. For example, for some customers (say, retail pharmacies), wholesalers negotiate volume discounts with the manufacturers that they can pass on to those customers. The distributors also offered promotions to their immediate customers, the pharmacies.⁶¹

As noted previously, three companies account for more than 92% of the market of distribution of pharmaceuticals in the U.S.: Amerisource Bergen, Cardinal Health, and McKesson.⁶² These distributors manage the flows of money that rely on a complicated system of reimbursements and chargebacks. In fact, 27% of total pharmaceutical sales were paid by manufacturers to various entities in the drug distribution channel in the form of cash payments, rebates, and chargebacks (due to complex pricing arrangements across the industry).⁶³ Moreover, wholesalers must provide enough value to compete with large, nationwide chains that serve their own distribution function for their many outlets (CVS, Walgreens, etc.).

Pharmacies negotiate discounts and rebates with both the manufacturers and the wholesalers based on sales volume/market share; they also negotiate with pharmacy benefit managers to be included in their networks. Retail pharmacies include chain pharmacies and mass merchants with pharmacies; independent pharmacies, and mail-order pharmacies. The largest retail pharmacies (e.g., CVS, Walgreens, Walmart) also offer wholesale services to their own retail stores. These accounted for 74% of retail prescriptions.⁶⁴ They may also coordinate their efforts with the three distributors above. I elaborate on the services the distributors offered to pharmacists in detail below.

Pharmacy benefit managers (PBMs) are used to help employers and other payers save on costs. PBMs account for about 2/3 of prescriptions in the U.S. Three Pharmacy Benefit Managers (PBMs) – CVS Caremark, Express Scripts, and UnitedHealth's Optum – have 73% of the PBM market.⁶⁵ Pharmaceutical distributors recognized the need to create value for group purchasing organizations; they have line-of-sight into the way PBMs operate, how they establish product lists for their formularies, what products insurance has denied, what switches pharmacists made from branded products to generics, etc.⁶⁶ By

⁶¹ Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Supply Chain* (2005). (Available at <https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>)

⁶² HDA, *The Role of Distributors in the US Health Care Industry* at 3.

⁶³ Dabora, Matan, Namrata Turaga, and Kevin Schulman, "Financing and Distribution of Pharmaceuticals in the United States," *JAMA*, July 4, 2017 at 21-22.

⁶⁴ Drug Channels Institute, *The Top 15 Pharmacies of 2015*, (2016). (Available at <https://www.drugchannels.net/2016/01/the-top-15-pharmacies-of-2015.html>).

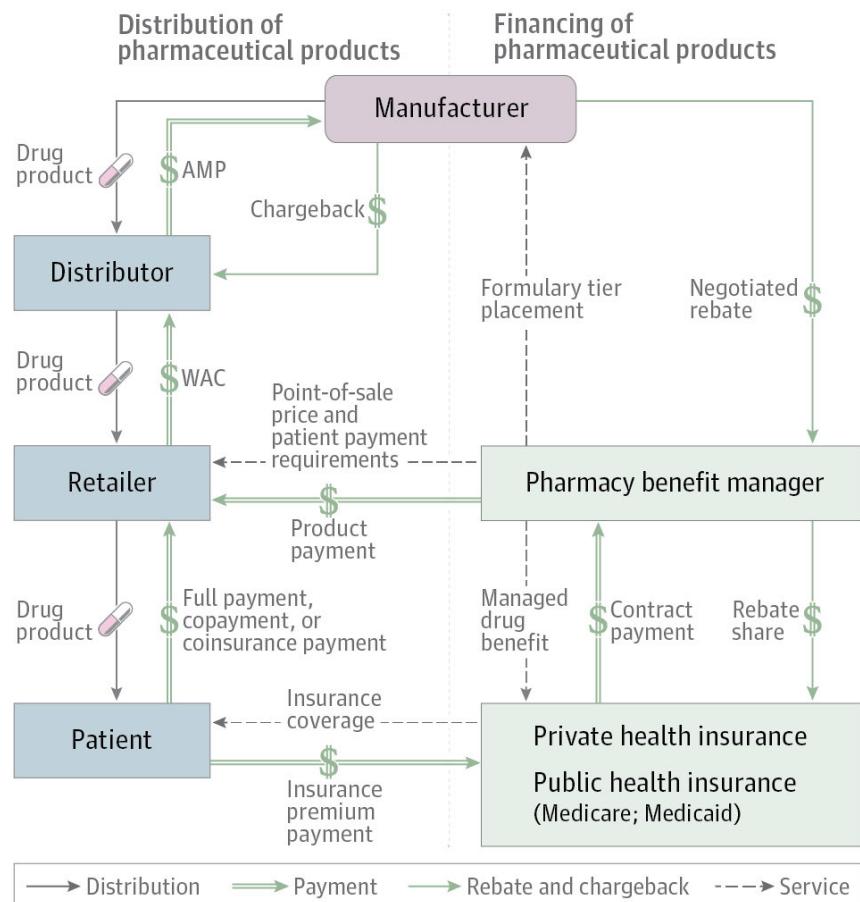
⁶⁵ Dabora, Matan, Namrata Turaga, and Kevin Schulman, *Financing and Distribution of Pharmaceuticals in the United States*, *JAMA* (July 4, 2017).

⁶⁶ Rollins, Brent and Matthew Perri, *Pharmaceutical Marketing* (2013) at Ch. 5.

cultivating relationships with these other powerful industry players, distributors further cement their role in providing value to the pharmaceutical companies.

Another depiction of how the physical/product flows are separated from the financial/monetary flows is illustrated in this report.⁶⁷

Figure. Flow of Pharmaceutical Funds, Products, and Services.*



* Adapted from a figure by the Congressional Budget Office, in Dabora, Turaga, and Schulman (2017) Services represent contractual relationships between entities; rebates are payments from manufacturers to pharmaceutical benefit managers; chargebacks are payments from manufacturers to distributors. Retailers include pharmacies, hospitals, group purchasing organizations, and mail-order programs. AMP indicates average manufacturer price; WAC, wholesale acquisition cost.

⁶⁷ Figure pulled from Congressional Budget Office (CBO), *Prescription drug pricing in the private sector* (January 2007). (Available at: <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf>)

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Unique considerations and challenges of pharmaceutical channels include the fact that end users (patients) don't make their own purchase decisions.⁶⁸ Instead, they get a prescription from physicians, who themselves typically don't stock/sell the product (except for some specialty pharmaceuticals that they administer via infusion/injection). The prescription is filled by a pharmacy, of which there is a wide variety, including mail order, large chains, small independents, etc. Insurance issues also complicate the payment system, and the various group purchasing organizations negotiate insurance rates and establish what pharmaceutical products can be reimbursed/at which rates.

The regulatory/legal environment is also a unique consideration in pharmaceutical marketing.⁶⁹ The Code of Ethics (previously noted) instills a higher burden of duty, given the nature of the product—particularly for drugs monitored by the Controlled Substances Act.⁷⁰ Under these conditions, marketers have a special responsibility to ensure strict controls in their distribution channel. In the opioid supply chain, the Distributors' privileged position requires responsibilities for monitoring and ensuring the security of the opioid supply chain ("maintaining effective controls against diversion").⁷¹ Indeed, as the opioid distributor's industry group describes, "distributors play a critical role in maintaining the integrity of today's closed-loop supply chain by consolidating manufacturer orders, delivering products to pharmacies, and processing returns."⁷² "Because distributors sit at the nexus between manufacturers and pharmacies, they support ecosystem efficiency and supply chain security by providing valuable transactional data."⁷³

As in any channel system, efficient flows of data and information are key to seamless coordination, but also for compliance with regulatory obligations. As summarized by the Healthcare Distributors Alliance, Distributors are uniquely situated in that they have visibility both up and down the supply chain, as shown in the Figure below.⁷⁴ Further, the HDA states, "[p]ositioned at the center of the supply chain, distributors have access to data from both upstream and downstream partners."⁷⁵

⁶⁸ Rollins, Brent and Matthew Perri (2013), *Pharmaceutical Marketing* (2013) at 111.

⁶⁹ *Id.*

⁷⁰ See Schedule 6.

⁷¹ *Id.*

⁷² HDA, *The Role of Distributors in the US Health Care Industry* at 9.

⁷³ *Id.* at 10.

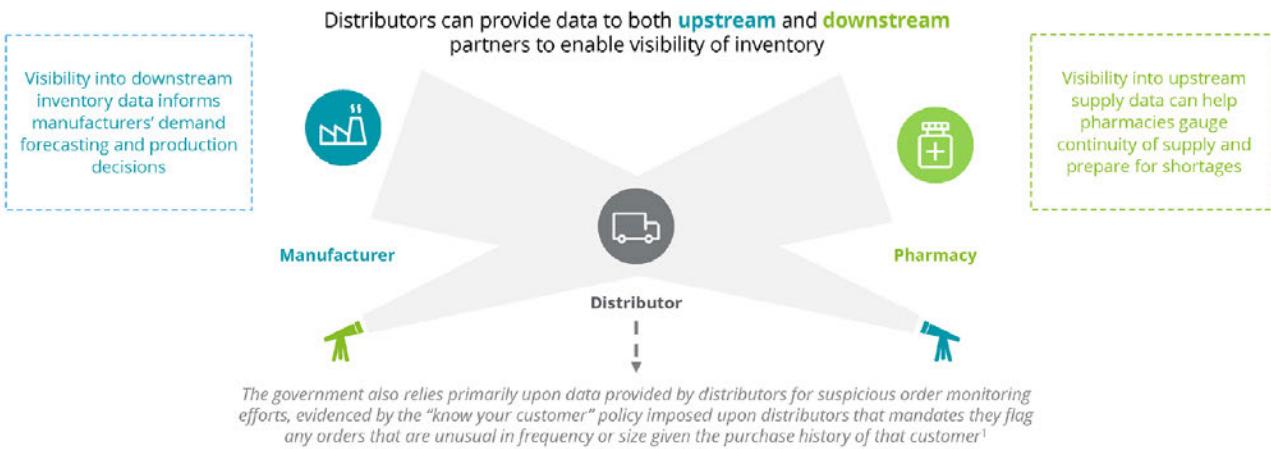
⁷⁴ *Id.*

⁷⁵ *Id.* at 20.

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Figure 6. Distributors support supply chain transparency and ecosystem efficiency

Distributor data opportunity at the nexus between manufacturers and pharmacies

Sources: ¹DEA Diversion Control Division, Deloitte analysis

For pharmaceuticals, the data regarding product flows are essential to calculating the amount of money manufacturers give back to distributors in the form of “chargebacks.” These monies are calculated as a function of the difference between the price customers negotiated with the manufacturers, and the price that the wholesaler charges. Since customers’ negotiated prices may be lower than wholesale prices, manufacturers make up the difference to make the distributor “whole” again.

Industry experts noted a change in the distribution part of the wholesalers’ business model (e.g., how they earned revenue) in the early 2000s. Traditionally, Distributors would hold inventory and, as prices increased, would make additional margin from having purchased mass volume at lower prices—essentially relying on price arbitrage to generate a portion of their profits. With the rise of generics and better information technology, the “industry abandoned the “buy-and-hold” model in favor of a fee-for-service model, in which wholesalers charge manufacturers for services rendered.”⁷⁶ This model “has led to increased market intelligence in the form of timely and accurate data from distributors. The pharmaceutical marketer (manufacturer) can then use this information to help in forecasting and customer service if any issues arise.”⁷⁷ The HDA notes, “Distributors could leverage this position and, similar to retail pioneers, build or acquire enhanced data capabilities that can help them develop a deeper customer understanding and meaningful insights.”⁷⁸

The visibility up and down the supply chain is a valuable asset to the Distributors. In fact, the Distributors have made significant investments in technology and platforms for pharmacists to effectively run their businesses—data and technology which could be used not only to increase sales but also to monitor such sales for problematic ordering trends.

⁷⁶ Rollins, Brent and Matthew Perri (2013), *Pharmaceutical Marketing* (2013) at 110.

⁷⁷ *Id.* at 111.

⁷⁸ HDA, *The Role of Distributors in the US Health Care Industry* at 20.

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Given their skills, data and capabilities, the Distributors served as a key business partner for pharmacies. The programs the Distributors offer the pharmacies include:⁷⁹

- Automated pharmacy dispensing;
- Data management services;
- Direct-to-customer order fulfillment;
- Pharmacy management systems and services;
- Generic sourcing;
- prescription data capture.

As the Distributors provide increased value to the pharmacies, they can leverage the knowledge, competencies, and relationships to provide increased value to the manufacturers as well. These competencies allow the Distributors to offer an array of consulting services, known as “value added services.”⁸⁰ The evidence presented in Section VI shows these value-added services include:

- leveraging the Distributors’ established communication channels with pharmacists to advertise the pharmaceutical products on the distributors’ platforms;
- leveraging the Distributors’ sophisticated understanding of the various players/actors in the marketplace to undertake research on the manufacturer’s behalf, and to make strategic recommendations based on the research implications;
- leveraging the Distributors’ knowledge of the insurance industry to create programs to switch/enhance “compliance” at the pharmacies via pharmacist intervention programs in which Distributors trained pharmacists to engage in behavioral methods to coach patients for “medication compliance;”
- leveraging the Distributors’ knowledge of sales and marketing to hire and train field sales teams to call on pharmacists on the manufacturers’ behalf;
- providing detailed assessments of the sales growth and return-on-investment of these various marketing initiatives.

In addition, the Distributors’ sophisticated understanding of the health care providers enabled them to design and publish peer-reviewed clinical studies in medical journals, and to design and execute speaker series and continuing education for health care providers in pain management (off the manufacturer’s books).

Despite their importance and market power, the trade press states that these Distributors “don’t capture the same attention that producers or retailers get; they often are considered the unsexy conduit between the two.”⁸¹ It is unsurprising then that they have flown under the radar until the recent opioid crisis.

⁷⁹ *Id.* at 13.

⁸⁰ Rollins, Brent and Matthew Perri (2013), *Pharmaceutical Marketing* (2013) at 109,

⁸¹ Britt, Russ, *Growing share of ‘Big Three’ gets federal attention: Giant wholesalers dominate market, to hit quarter-trillion mark in sales*, Marketwatch (May 30, 2007). (Available at <https://www.marketwatch.com/story/growing-share-of-big-three-drug-wholesalers-gets-attention>)

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VI. The Distributors' Played a Significant and Integrated Role in Pharmaceutical Marketing

Each of the Distributors has tried to characterize its role in the opioid supply chain as limited to shipping, logistics and order fulfillment. Indeed, each Distributor's executive publicly made emphatic statements about their company's purportedly limited role.

AmerisourceBergen has repeatedly stated in the press that Amerisource "does not . . . market these [opioids] or take any action to create demand for their use."⁸² ABDC CEO Steve Collis published an op-ed in 2017 stating "We [ABDC] don't manufacture [opioids], provide them directly to patients or take any action to drive their demand."⁸³

McKesson's CEO John Hammergren stated in his Congressional testimony in 2018 that, "[a]s a distributor, McKesson does not manufacture prescription drugs, and we do not market them to doctors or patients. Nor do we market any particular category of drugs, such as opioids, to pharmacies."⁸⁴

Likewise, in his May 8, 2018 Congressional testimony, Cardinal Health's former Chairman of the Board and Chief Executive Officer George Barrett stated, "Cardinal Health, in its role as a pharmaceutical wholesale distributor, does not manufacture medications or market them to patients.... As an intermediary in the pharmaceutical supply chain, Cardinal Health does not ultimately control either the supply of or the demand for opioids."⁸⁵ In addition, in an internal letter to all Cardinal Health employees regarding the 60 Minutes and Washington Post coverage of the opioid epidemic, CEO George Barrett wrote,⁸⁶ "As a wholesale distributor, we do not manufacture, promote or prescribe medications to the public."

It appears this statement was coordinated, as the Distributor's industry association, the HDA's statement also says: "...distributors do not manufacturer, prescribe, or promote medicines."⁸⁷

The evidence presented below and cited in Schedule 5 to this Report, however, shows that the Distributors were integrally involved in marketing opioid products.⁸⁸ The evidence shows that opioid manufacturers relied on the Distributors as key marketing partners in growing demand for opioids (Sections A and B below), including ensuring patients "complied" with their prescribed opioid prescriptions.

⁸² See HDA_MDL_000013887 (8/24/17 Cincinnati Enquirer op-ed by Gabe Weissman).

⁸³ ABDCMDL00359830 (9/21/17 Linked In op-ed by CEO Steve Collis).

⁸⁴ See MCKMDL01387750 (May 8, 2018 written testimony of John Hammergren, McKesson CEO); MCKMDL01287757

⁸⁵ Hearing Before the United States House of Representatives Committee on Energy and Commerce, Testimony of George S. Barrett (May 8, 2018). (Available at <https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-BarrettG-20180508.pdf>).

⁸⁶ CAH_MDL2804_00112004

⁸⁷ <https://www.hda.org/news/hda-blog/2018/09/27/15/32/2018-09-27-understanding-our-role-in-the-supply-chain>

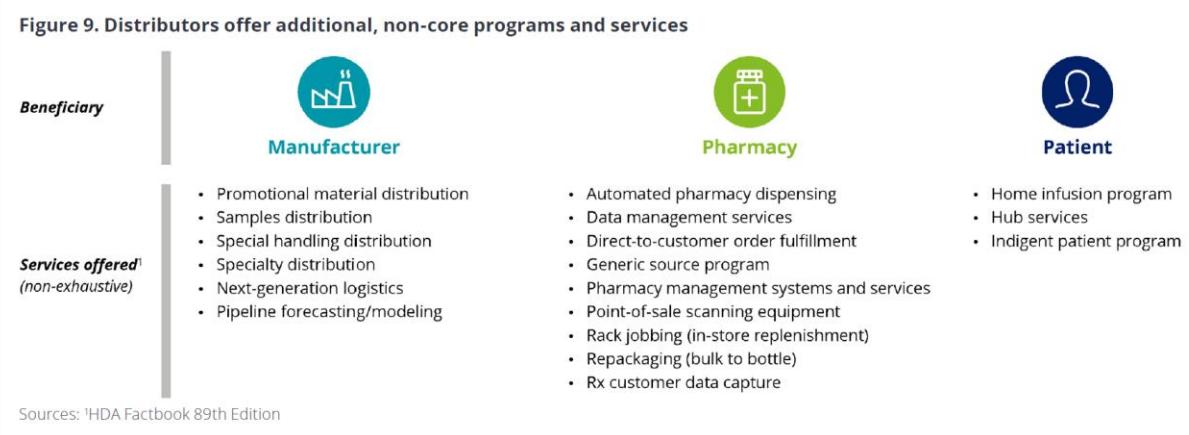
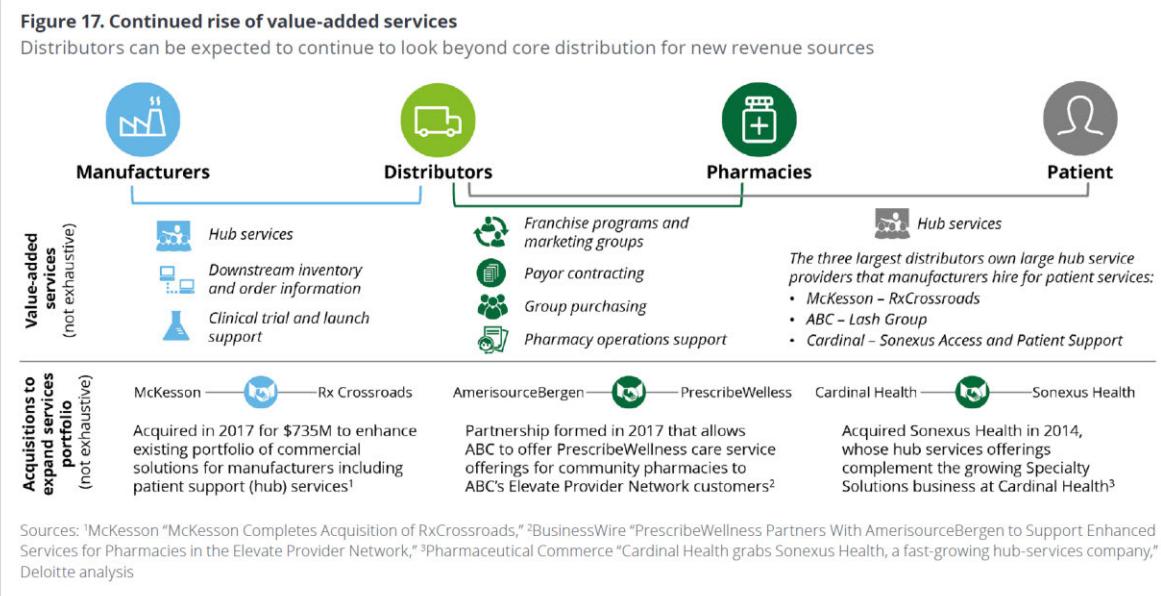
⁸⁸ Documents supporting my opinions in this Section are listed in Schedule 5 to this Report and cited herein.

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The evidence shows that from the mid-1990s to present, the Distributors were involved in a vertically integrated supply chain with the opioid manufacturers to grow the demand for prescription opioids, maintain that demand, and ensure that supply met that demand. Their efforts were part of an integrated supply chain where all parties collaborated to drive the demand for prescription opioids, to the benefit of all opioid supply chain participants.

To the extent any of these companies claim they did not participate in marketing opioids, the evidence below shows those statements are false.

The Distributors' association, the Healthcare Distributors Alliance, makes clear that the Distributors "do much more than serve as the intermediary that ships products from manufacturers to pharmacies and providers," including offering a broad range of services the distributors offered to increase demand, including through marketing,⁸⁹ as shown in the Figures below.



⁸⁹ HDA, *The Role of Distributors in the US Health Care Industry* at p.3, 13, 20.

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The Distributors effectively leveraged their deep knowledge of pharmacists' businesses to provide a variety of marketing and value-added services for the pharmaceutical manufacturers (including the main opioid manufacturers), which moved well beyond mere order taker and fulfillment houses.

In particular, the evidence cited herein and in Schedule 5 to this Report shows that Distributors worked to stimulate demand through engaging in a variety of sophisticated marketing strategies and offering value-added services to opioid manufacturers designed to grow the prescription opioid market, including the following (Section C below):

1. Establishing retail relationships and leveraging those relationships to market and promote prescription opioids.
2. Providing market research and analysis services to opioid manufacturers.
3. Developing strategic marketing plans for opioid manufacturers, including segmentation analysis and value proposition design.
4. Performing direct marketing for opioid manufacturers:
 - a. Advertising manufacturer partners' opioid products to the retail pharmacies.
 - b. Implementing sales-promotions (offering coupons and rebates) to customers for opioid products.
 - c. Managing field sales personnel, and other personal selling strategies
5. Performing indirect marketing by leveraging sophisticated strategies to facilitate the opioid manufacturers' influence with pharmacists, patients, and doctors, including:
 - a. Training in behavioral coaching techniques to ensure patient compliance with prescribed medications.
 - b. Offering continuing education programs for physicians, pharmacists, and healthcare providers promoting the widespread use of opioids.
 - c. Hiring and training key opinion leaders (speaker series) to promote the widespread use of opioids.
 - d. Creating/funding clinical trials and publications with the purpose of influencing physician attitudes towards broader opioid prescribing.
 - e. Working through the industry trade associations to ensure favorable operating conditions and promoting the widespread use of opioids.

The Distributors were compensated for performing these marketing services with fee-for-service arrangements as well as a percentage of the sales lift their marketing programs generated for the manufacturers' products (see Section D below). Hence, the Distributors were not "neutral" actors and had a strong financial incentive to grow demand, and thus sales, of opioids.

Moreover, the Distributors provided solid evidence that their marketing efforts resulted in a significant return-on-investment and sales growth for the opioid manufacturers (see Section D below).

A. Manufacturers and Distributors Team Up in an Integrated Marketing System

Recall from Section IV, effective marketing is based on an integrated approach to distribution channel strategy in which all entities function as if they were one. The goal of achieving coordination, of all members acting in concert, translates into higher volume and higher margin.

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Numerous internal documents from the opioid manufacturers and Defendants' own documents provide evidence of the critical role of the Distributors in the growth of the prescription opioid market starting in the mid-1990s and continuing today.⁹⁰ From the beginning of the dramatic expansion of the prescription opioid market, the opioid manufacturers recognized the important role Distributors played in their market success, relying on these Distributor partners to facilitate their downstream marketing efforts. Some notable examples follow.

Purdue

In his "OxyContin Pre-Launch Meeting" notes from May 26, 1995, Purdue's National Accounts (national accounts = distributor accounts) manager summarized the purpose of the sub-committee is to "ensure retail distribution of OxyContin within the first 30 days of release."⁹¹ The memo details 12 key points of pre-launch demonstrating the integral role of the Distributors in the launch and strategy to grow demand for Oxycontin:

1. Selling efforts focused on a list of 10 distributors and retailers;
2. Explore whether the "marketing and sales" [team] could visit these 10 accounts;
3. Create a sell sheet to "sell in" the product to wholesalers, in accordance with guidelines issued in G. R. Green's 5/22/95 memo.
4. Offer a percent bill back to wholesalers based on stocking at a certain level;
5. Increase the number of speaker programs to 30-40 for the National Account Group; pursue this speaker program through sponsorship at McKesson or Bergen;
6. Evaluate wholesaler programs to "enhance the launch and distribution" including AccuSource from Bergen and MTS Telemarketing from McKesson;
7. "Dating and off-invoice allowances would have to be segregated under separate purchase order which would be "difficult to do with one DEA form coming in for multiple narcotics." M. Innaurato would reemphasize the need to segregate orders for dating terms granted during this promo.
8. National accounts sell-in effort will begin in Sept; need to train National Account Managers with "feeder mailing" as soon as possible;
9. Review pre-launch sell-sheet with Legal;
10. Wholesaler sell-in appointments begin in September;
11. Change of products over to Purdue as a vendor with trading partners must be established to get an item number for OxyContin; and
12. Chain drug warehousing allowance for distribution is possible allowing them to buy Class II directly to distribute to store level.

A December 1995 Bergen email (now ABDC) discussed the use of a "glimmer" button on Bergen's Accusource System for Purdue during the month of January; whenever a pharmacist typed in one of 25 targeted competitors' brands, pushing the button would reveal information on Oxycontin to the pharmacist.⁹² (This sophisticated use of technology to target ads based on a competitor's brand name occurred even before targeted, pay-per-click advertising had been invented.)

⁹⁰ See Schedule 5, Table A.

⁹¹ PKY180255278

⁹² PDD8801142910

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As early as 1997, Purdue circulated a memo documenting the integral role the Distributors were playing in its opioid marketing and the value-added services they provide that go far beyond logistics:

*"Wholesale partners are moving away from simply performing distribution; they are becoming Information vendors; they have information on compliance, substitution, patient demos they want to sell us."*⁹³

Purdue summarized how McKesson, ABDC, and Cardinal each worked with Purdue to market its opioid drugs, including through advertising, trade show marketing to its retail customers, rebates, coupon programs, direct mail programs, literature fulfillment programs, customer programs, and product placement.⁹⁴ Other documents similarly illustrate the partnership between Purdue and the distributors to drive demand through marketing throughout the early years of selling Oxycontin.⁹⁵ Internal documents illustrate how the retailer and wholesaler margins were being squeezed and that Distributors were turning to offering value services such as marketing to increase their revenue.⁹⁶

The Distributors were integrally involved in the launch and increase in demand for Oxycontin. For example, in August 2000, Purdue worked with Bergen (ABDC) through Bergen's managed care division to "help educate retail pharmacists throughout their network (1800 stores)," including distributing literature designed to promote the use of opioids.⁹⁷ According to Purdue, this partnership with ABDC "provides us a good opportunity to educate patients on why this medicine is appropriate vs. questioning why the patient was prescribed. To attain this will be by effective pull through, and this is critical to the success of the program. George Sanders would like feedback on how program was received at the field level."⁹⁸

Similarly, in 2001, Purdue's head of National Accounts and Trade Relations gave an internal presentation explaining how National Accounts & Trade Relations is "a selling partner responsible for largest customers committed to working with you to drive the selling process;" the presentation provided data on the top wholesalers, the services wholesalers offer, and the number of retail accounts they serve. In his presentation, Purdue executive Stephen Seid noted that the 2001 goals include educational opportunities/continuing education for pain management; a major chance to educate pharmacists; and Purdue's commitment to participate in Bergen's Cancer Pain Management program/trade show with the goal of "spreading the good word of Purdue to our trade customers."⁹⁹

In January 2008, Purdue let Amerisource Bergen know that it had fallen behind the other distributors in its marketing of Oxycontin, stating that "Quite frankly we need something from ABC to assist us with our launch of our new sizes of OXYCONTIN. Nearly all other wholesalers are bombarding us with ideas and programs to drive their (and our) sales forward. It is embarrassing to me personally that we have nothing from ABC when we begin shipping one week from today."¹⁰⁰ Amerisource Bergen then

⁹³ PKY180256902

⁹⁴ PKY180256902; PPLPC030000271126; PPLPC009000007590; PKY180256902; PPLPC029000022136; *see also* PDD8801281191; PPLPC008000013580; PPLPC004000145999; PPLPC004000146529

⁹⁵ PKY181284712

⁹⁶ *Id.*

⁹⁷ PPLPC029000022136; *see also* PDD8801281191

⁹⁸ PPLPC029000022136; *see also* PDD8801281191

⁹⁹ PPLPC008000013580

¹⁰⁰ PPLPC004000145999; PPLPC004000146529

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apologizes for tardiness and proposes a three-point program for Purdue, including mailing to 5000 ABC customers; an online post to promote the new items and rebate offer on The Link for all ABC customers; and an “Alert Notice” on Feb. 1 to ABC sales team regarding the new items and rebate.¹⁰¹

Purdue also relied on the Distributors to field its continuing education seminars, both through locating seemingly impartial speakers and through funding.¹⁰²

In 2015, Purdue circulated an internal memo documenting an “upcoming customer meeting with the McKesson Executive Team,” on October 19-20, 2015. The importance of their collaboration with McKesson was conveyed in the meeting objectives: demonstrate Purdue’s intent to work with major organizations like McKesson and surface opportunities for collaboration.¹⁰³

TEVA

TEVA similarly relied on the Distributors for its opioid marketing. In April 2016, TEVA’s slide deck regarding its distribution model for IR hydrocodone listed the channel objectives to align distribution with the overall brand strategy; to place the product deep into the channel at launch; to create trade/channel solutions for the duration of the product life cycle; and to offer seamless coordination with TEVA Pain service providers to ensure alignment with strategy.¹⁰⁴

ENDO

Endo similarly viewed the Distributors as strategic partners in the growth of the opioid market. For example, in February 2012, Endo had a business plan to “identify opportunities for a long-term relationship with McKesson to bring in continuous sales and strategic partnership opportunities.”¹⁰⁵ Developed by Kayla Kinhofer (Trade National Accounts at Endo), the document (p. 4) states objectives as:

1. Increase/expand product and unit distribution of all brands and specialty products
2. Increase overall revenue through McKesson business solutions offerings
3. Establish/achieve vertical integration of Endo products across 3-4 major McKesson Divisions
4. Increase access of specialty products to hospitals; remove access barriers; increase awareness
5. Use RelayHealth to support sluggish brands.

The report also provides an overview of McKesson’s revenue, customer base, product/service offering, and it details key issues and opportunities for a partnership. Through “increased direct-to-pharmacy communication about Endo to build product awareness and develop deeper relationships,” a partnership would build market confidence, awareness, and reputation of Endo products; increase sales/ grow business by utilizing all McKesson divisions; negotiate better contract terms; leverage relationships; highlight total Endo financial contributions to McKesson; renegotiate service fees.... Other

¹⁰¹ *Id.*

¹⁰² PPLPC004000183541

¹⁰³ PPLPC034001107535

¹⁰⁴ TEVA_MDL_A_13495736

¹⁰⁵ ENDO-CHI_LIT-00088728

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strategies (p. 6) include a cross-functional relationship between the companies, a cross-selling model, and the report identifies critical success factors (p. 7).¹⁰⁶

Johnson & Johnson

Nucynta ER's Director of Trade Operations (Frank Mashett) shared information on Wholesaler and Retail Pharmacy Programs (June 2011),¹⁰⁷ including data on 2009 Top 11 retail pharmacies; these included AmerisourceBergen's Good Neighbor program, Cardinal's Leader program, and McKesson's Health Mart pharmacies. His slide deck further detailed the number of stores in the retail pharmacy market and the amount of revenue flowing through each type of store (traditional chains, independents, etc.). This J&J report also details each Distributor's "communications programs" available to pharma manufacturers seeking to market to these pharmacy chains.

B. Distributors Bring a Wide Variety of Marketing Services to their Partnership with Opioid Manufacturers

As noted in Section IV, to assure maximum market penetration, manufacturers rely on Distributors to be part of their marketing efforts. In order to facilitate these marketing efforts, opioid manufacturers offered the Distributors a variety of incentives including merchandising allowances and other price deals to bring their services to the partnership to sell opioids. These financial incentives aligned the manufacturers' and Distributors' interests so that both parties benefited as opioid sales increased.

In their partnership with the opioid manufacturers, the Distributors offered and performed a wide variety of marketing services in support of the growth and maintenance of demand for prescription opioids and to increase opioid sales. The Distributors highlighted these services in their own marketing materials. The Evidence forming the basis of the opinions in this Section appears in Schedule 5, Table B.

Cardinal Health provides a full array of marketing services summarized in its July 2013, "Overview of Manufacturer Marketing Services,"¹⁰⁸ outlining awareness programs targeting pharmacists (via Service Flash, RxDeals, Order Express, and DirectMail); awareness programs targeting Pharmacists, Physicians and Nurses (eConnection), and awareness programs targeting consumers (Pharmacy Health Network). As detailed in Section II previously, "awareness programs" refer to advertising to generate familiarity with the manufacturers' products through these various channels to increase demand for those products.

Cardinal Health also offered and provided telemarketing services for opioid products. Cardinal summarized these services in its own advertising, sending a "Service Flash" (presumably to their vendor/manufacturer partners) in 2011, letting them know that "Telemarketing is back!" offering vendors the opportunity to "reach over 2,900 of our Retail independent and Medicine Shoppe Customers."¹⁰⁹ "All calls are placed by Cardinal Health employees, so the customers have an established relationship with the callers; Telemarketing is a great way to enhance your existing marketing programs

¹⁰⁶ *Id.*

¹⁰⁷ JAN-MS-00465772

¹⁰⁸ ENDO-CHI_LIT_004770118

¹⁰⁹ CAH_MDL2904_00134451

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and to increase company and product awareness within our Retail Independent and Medicine Shoppe customer base.”¹¹⁰

Similarly, **McKesson’s brochures** and promotional slide decks detailed its BrandRx Marketing Services for “Manufacturer Marketing.” For example, in a 2015 overview of marketing tools and channels,¹¹¹ McKesson highlighted the various messaging and awareness programs manufacturers could use to reach all the pharmacies in its own pharmacy network (Health Mart), including online advertising, articles, direct email, and consumer online ads (via McKesson Connect) and its DirectRX program (banner ads targeted to pharmacists) and connected to its online ordering portal; its RXDetail program (telemarketing and on- hold messaging); and its MarketingHUB (a tool for Health Mart pharmacies to order marketing and share promotional tools for the manufacturer’s brand).

In a 2010 brochure, **McKesson Customer Solutions for Driving Brand Performance**,¹¹² McKesson advertises that “McKesson Manufacturer Marketing partners with pharmaceutical manufacturers to define and execute customized strategic solutions targeting key awareness, distribution, sales and adherence goals at all stages of the product life cycle.” It features “strategic solutions [to] deliver the resources and expertise to help your brand:

- Educate pharmacists (whether independent, hospital-based, or in long-term care facilities) on brand attributes and clinical information;
- Enhance pharmacists’ brand awareness through multiple communication platforms, most linked to the McKesson Connect online ordering portal;
- Increase product distribution to retail pharmacies through targeted product launch, distribution, and packaging solutions;
- Build patient awareness through retail merchandising, promotion, and advertising; Improve patient adoption by fostering new trial usage;
- Measure ROI that surface and support continuing refinements.¹¹³

In a proposal for TEVA, McKesson highlighted the following skills/capabilities it offers manufacturers:¹¹⁴

- existing customer relationships with pharmacists;
- “turnkey implementation process” for program execution;
- “leverage McKesson’s unprecedented connectivity in the marketplace,”
- “proven and innovative solutions from multiple McKesson business units that offer strategic solutions to deliver resources and expertise to help your brand educate pharmacists on brand attributes;
- brand awareness through multiple communications platforms, online ordering, in-store promotions,
- measure ROI (return on investment) of the marketing activities to provide metrics to support strategy refinements.

¹¹⁰ *Id.*

¹¹¹ MCKMDL00724395

¹¹² CAH_MDL2804_02100389

¹¹³ *Id.*

¹¹⁴ TEVA_MDL_A_12746422; MCKMDL00353374

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McKesson offers an “unmatched combination of communication, promotion, distribution and targeted analytics of exclusive data to help TEVA ... maximize profitability; target awareness, sales and distribution goals at all stages of the product life cycle; build confidence in pharmacists in recommending TEVA products.” Other services include RX Rapid Research (conduct focus groups via fax to provide feedback on your brand and market issues);¹¹⁵ OrderDirect Messaging to help your brand capture more sales and support patient safety. “McKesson Manufacturer Marketing backs your brand with expertise to increase brand performance from more than 25 programs. Create the communication & distribution strategy to deliver measurable results.”¹¹⁶

McKesson’s blog also states that “data management services are essential business intelligence offerings to manufacturers” and in fact, data management services are the only services (out of all the different programs and services distributors offer) that distributors provide to both manufacturers and other customers.¹¹⁷

McKesson’s analysis of risks highlighted the importance of data to its integral role in connecting manufacturers to downstream healthcare entities (pharmacies, hospital and clinic administrators, payors, healthcare providers, etc.). McKesson’s 10Ks for 2001-2017 consistently identify data and IT systems as key concerns, including “the failure of our healthcare technology business to keep up with technological advances,” and “dependence upon sophisticated IT systems,” risks from “interruptions to customers’ access to data,” risks from “data security incidents.” In addition, it cites “regulation of our distribution business” could negatively impact our business.¹¹⁸

As part of its efforts to be an essential element of the healthcare landscape, McKesson also had a subsidiary business unit, **InterQual**. InterQual is generally described as an evidence-based clinical decision support solution to help payers, providers, and government agencies make clinically appropriate medical utilization decisions (sometimes referred to as CPG or clinical practice guidelines). From 1998 to 2016, InterQual was owned by McKesson Corporation. In March 2017, McKesson engaged in a transaction with Change Healthcare that combined Change Healthcare Holdings, Inc. and most of McKesson Technology Solutions.¹¹⁹ McKesson owned approximately 70% of this new company.¹²⁰

InterQual was important because: “With businesses and customers that span all settings of healthcare, McKesson has a unique 360-degree view of the healthcare system ready to go to work for you. Our clinically integrated solutions help simplify, automate, and transform healthcare across the care,

¹¹⁵ TEVA_MDL_A_12765924

¹¹⁶ TEVA_MDL_A_12765926

¹¹⁷ <https://www.mckesson.com/Blog/10-Pharmaceutical-Distribution-Trends-to-Know/>

¹¹⁸ Form 10-K McKesson Corporation, years 2001-2017.

¹¹⁹ *McKesson and Change Healthcare Complete the Creation of New Healthcare Information Technology Company*; Mar. 2, 2017; <https://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-and-change-healthcare-complete-the-creation-of-new-healthcare-information-technology-company/>; see also <https://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-and-change-healthcare-announce-new-company-named-change-healthcare/>; <http://tmsearch.uspto.gov/bin/showfield?f=doc&state=4808:jj28ao.2.1>

¹²⁰ <https://www.nashvillepost.com/business/health-care/information-technology/article/20826776/change-mckesson-division-joining-forces>

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revenue and payment cycles, from the front-end to the back-end, for better health.”¹²¹ InterQual’s support system, InterQual Connect (developed in 2015) allowed so payers to automate authorization requests, even those requiring medical review, allowing providers to receive quicker authorization approvals for most requests.¹²² Payers only need to “touch” exceptions that cannot be approved automatically.¹²³

As the later evidence shows, the ability to influence/control the clinical practice guidelines for pain management, to manage insurance exceptions for prescriptions, and to switch prescriptions based on cost of copays (“denial conversions”) all were part of McKesson’s role in the opioid epidemic.

Amerisource Bergen (ABDC) prepared “The Playbook” (October 2017) for its health systems, with a goal to “work collaboratively across legacy business units to support the strategy and its sales team.”¹²⁴ This Playbook is quite sophisticated, and uses the slogan “Where knowledge, reach, and partnership shape healthcare delivery.”¹²⁵ In March 2018, ABDC hired McKinsey (a widely-known strategy consultancy) to support the firm’s “enterprise transformation,” including understanding “all the marketing services we offer to our manufacturers.”¹²⁶ The file prepared for McKinsey includes:¹²⁷

- a Marketing Services price list for “CustomerConnect” including calls and research, email marketing, display ads and sponsored content on ABC various online sites (*see* list);
- printed communication and direct mail as well as invoice inserts (e.g., ads that are included in invoices); and
- print advertising/editorial marketing in their three magazines (InsideOut reaches 17,000 healthcare systems and providers; Retail Remedy reaches 4000 pharmacists; Health Connections, reaches 135,000 GoodNeighbor pharmacy patients).

ABDC also offers ION Pricing (ION is a specialty Group Purchasing Organization focused on oncology (*see* Excel file regarding meetings/conferences to physicians)) and dispensing data.¹²⁸

The documentation provided to McKinsey also includes a Besse medical marketing services guide and a CustomConnect powerpoint deck to “improve product and brand performance through multi-channel promotion and education” (2018).¹²⁹

In “Inside our Business” (a manual, of sorts), ABDC highlights all of its various business units (*see* its Table of Contents).¹³⁰

Amerisource Bergen’s Marketing Code of Conduct notes that “in connection with its distribution activities,” certain ABDC subsidiaries “may perform Brand Rx Promotion-related activities” that implicate

¹²¹ InterQual 2016 Brochure

¹²² Fact Sheet IQ Connect; McKesson.com; *see also* InterQual 2016 Brochure

¹²³ Fact Sheet IQ Connect; McKesson.com

¹²⁴ ABDCMDL00323116

¹²⁵ *Id.*

¹²⁶ ABDCMDL00320055

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ ABDC-WVFED00018369.

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the PhRMA Code, OIG Guidance, and state laws related to Brand Rx Promotion" (p. 1).¹³¹ Its Code also states that an increase in the number of prescriptions ("over prescribing") or drug switching could inappropriately increase healthcare costs. Its Code prohibits financial support to third-party organizers of educational/professional meetings related to Brand Rx Promotion; prohibits control over selection of content, faculty, and materials. Similarly, if consultants are retained for Brand Rx Promotion, retaining such professionals who are involved in setting formularies or developing clinical practice guidelines must declare their engagement for two years afterward.

ABC's Lash Group "is one of the largest patient services organizations;" its approach is "focused on the delivery of accurate and timely information to patients, pharmacists, and physicians."¹³² Its philosophy is that "the most successful support programs are those that fit seamlessly within the needs of the manufacturer," "we see each partnership as a journey;" "we collaborate with our partners to meld a long-term strategic partnership over the entire product life cycle."

In 2004, ABC acquired Imedex, an accredited provider of physician continuing medical education. In the press release, R. David Yost, AmerisourceBergen Chief Executive Officer stated, "Imedex's outstanding array of physician education services continues our commitment to add incremental services that support manufacturers and healthcare providers along the pharmaceutical supply channel." "Imedex ... brings an attractive combination of highly regarded proprietary programs and client services for physicians, international scope and solid growth."¹³³

During the time that Imedex was owned by ABC, opioid manufacturers provided grants to and sent employees to Imedex CMEs.¹³⁴ It was clear that opioids and an opioid-friendly message was being promoted at these CMEs. For example, despite the fact that the grant agreements above explicitly stated that Teva's products were not to be promoted at the conferences, each agreement contained descriptions of Fentora and/or Actiq as well as their uses. Teva included its grants to Imedex under its marketing budget and gives the reason for such payments as "pain management."¹³⁵

Endo also worked with Imedex to advance the pro-opioid message. In one example, an Endo marketing plan included discussion of an Imedex symposium on the use of opioids, at which Endo presented on its new opioid product.¹³⁶ At another point, an Endo representative sought to provide information on Endo's products and notes on a doctor's presentation to a presenter at an Imedex CME; however, she noted that CME regulations prevented Endo from sending that information directly to the presenter. Instead Endo sent that information to Imedex to forward to the presenter.¹³⁷ Endo also relied on two

¹³¹ ABDC-WVFED00018369. (May 2009 Code; see also 2015 Code).

¹³² TEVA_MDL_A_11786072

¹³³ Business Wire, *AmerisourceBergen Acquires Imedex, Inc.; AmerisourceBergen Adds Accredited Physician Education Services* (May 10, 2004).

<https://www.businesswire.com/news/home/20040510006056/en/AmerisourceBergen-Acquires-Imedex-AmerisourceBergen-Adds-Accredited-Physician> accessed July 19, 2020.

¹³⁴ See e.g. See TEVA_MDL_A_06758021; TEVA_MDL_A_06764971; TEVA_MDL_A_06769509; TEVA_MDL_A_06771229; TEVA_MDL_A_06772174; TEVA_MDL_A_06794030; PKY180796664; PKY180947495; PPLPC05600009410.

¹³⁵ See TEVA_MDL_A_01180335; TEVA_MDL_A_00825736.

¹³⁶ EN3202. ENDO-OPIOID_MDL-04097240.

¹³⁷ ENDO-OPIOID_MDL-02261219; ENDO-OPIOID_MDL-02261221; ENDO-OPIOID_MDL-02261223.

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Imedex publications to support the “need for new pain medications to treat patients with malignant pain” in 2002 when looking for marketing materials for its EN3202 product.¹³⁸

Purdue often supported Imedex’s “Pain Management and Chemical Dependency Conference.”¹³⁹ Purdue worked with Imedex as late as 2011 to promote its opioid agenda.¹⁴⁰

Additionally, on April 3, 2007, ABC acquired Xcenda, “a strategic consulting firm” whose purpose was to “enhance the company’s existing manufacturer services businesses and providing additional capabilities in the key areas of pharmaceutical brand services.”¹⁴¹ Its website states, “whether it’s working on a product launch strategy or developing a disease-awareness campaign, our team of scientists and clinicians, health policy analysts, reimbursement experts, and communications specialists apply health economics and outcomes research to help you [pharmaceutical brands] develop a compelling total value proposition and successfully commercialize your product.”¹⁴² They offer services in:¹⁴³

- Health Economics and Outcomes Research;
- Real-World Evidence Generation;
- Market Access Consulting and Communications;
- Reimbursement & Policy Insights (strategy, payer segmentation);
- Global Market Intelligence;
- Field Services and Provider Education (field associates help physicians understand/overcome patient access barriers);
- Quality Strategy and Tactics;
- Advisor Networks; and
- Training.

Xcenda hosts seminars and conferences for the manufacturers on “successful commercialization using real-world evidence in product planning.”¹⁴⁴

Additionally, in 2016, a press release noted that Xcenda was unveiling new service offerings to enhance manufacturers’ market access strategies for specialty products.¹⁴⁵ A May 21, 2019 press release said that Xcenda had acquired Dymaxium, a company that specializes in the exchange of evidence and information between payers and manufacturers through its FormularyDecisions.com platform. Xcenda’s President stated, “We are constantly searching for innovative offerings that make this exchange of information between pharma and payers simpler and more efficient. We are thrilled to make this a

¹³⁸ ENDO-OPIOID_MDL-04093787.

¹³⁹ See PKY180796664; PKY180947495; PPLPC05600009410.

¹⁴⁰ PPLPC019000518994.

¹⁴¹ Biospace, *AmerisourceBergen to Acquire Xcenda LLC for \$25M* (April 3, 2007).

<https://www.biospace.com/article/releases/amerisourcebergen-to-acquire-b-xcenda-llc-b-for-25m-/>, accessed July 16, 2020.

¹⁴² Xcenda, *Who We Are*. <https://www.xcenda.com/about-us-who-we-are>; accessed July 16, 2020.

¹⁴³ <https://www.xcenda.com/solutions>

¹⁴⁴ *Id.*

¹⁴⁵ AmerisourceBergen, *Xcenda Unveils New Service Offerings to Enhance Manufacturers’ Market Access Strategies for Specialty Products* (July 12, 2016).

<https://www.amerisourcebergen.com/newsroom/press-releases/xcenda-unveils-new-service-offerings>.

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reality through this acquisition with Dymaxium's FormularyDecisions.com and the AMCP [Academy of Manage Care Pharmacy] eDossier System.”¹⁴⁶

To differentiate the services offered to the manufacturers, the Distributors compiled detailed competitive intelligence on each other’s operations. For example, Cardinal Health gathered “Strategic Intelligence” containing “gold standard information about the competitive environment.”¹⁴⁷ Cardinal tracked competitor profiles of both McKesson and AmerisourceBergen (among others) with an assessment of each competitors’ strengths and weaknesses and insights about their strategies.¹⁴⁸ Cardinal Health also developed a competitive intelligence briefing¹⁴⁹ on a conference that ABC held; ABC’s conference was on “TransPHARMation,” partnerships and adherence. Cardinal Health noted ABC’s partnership with The Creative Pharmacist as providing access to tools and education opportunities to help increase engagement with patients who have chronic illnesses. At this conference, ABC also announced GNP U (Good Neighbor Pharmacy University), ABC’s online learning portal offering education sessions for pharmacists and staff members.¹⁵⁰ These insights about the Distributors’ downstream relationships were also a key part of their strategy.

C. Specific Ways in which the Distributors Worked to Create Demand¹⁵¹

In their role as channel intermediaries, Distributors connect upstream suppliers (pharma manufacturers) to downstream customers (pharmacies). Pharmacies are a key customer group the distributors serve. They were also a key group that the opioid manufacturers needed to access as part of the industry’s effort to drive and then maintain overall demand for prescription opioids. The Distributors did more than merely fulfill pharmacists’ orders; they also provided a variety of value-added services to all members of the supply chain. The relationships and knowledge Distributors have of these downstream customers are a key asset that Distributors leverage in providing value for the opioid manufacturers.

1. First, the Distributors’ value-added services to pharmacists are highlighted because they were designed to grow demand for and facilitate dispensing of the drugs that the Distributors and their manufacturer partners were selling, including prescription opioids. These relationships and the Distributors’ specialized knowledge, as well as the technology that connected the Distributors to the pharmacies and the data those connections provided, became key sources of value to the opioid manufacturers; more specifically, these connections allowed the Distributors to provide fee-for-service advertising to the opioid manufacturers to advertise and deliver sales promotion offers to the pharmacists and their patients.
2. Second, as part of their value-added services provided to the opioid manufacturers, the Distributors performed sophisticated market research on physicians, payers, pain specialists, patients, health care

¹⁴⁶ AmerisourceBergen, *Xcenda Enhances Value Exchange between Payers and Manufacturers with Acquisition of Dymaxium* (May 21, 2019) <https://www.amerisourcebergen.com/newsroom/press-releases/xcenda-dymaxium-acquisition>, accessed July 19, 2020.

¹⁴⁷ CAH_MDL2804_01384291

¹⁴⁸ *Id.*

¹⁴⁹ CAH_MDL2804_00104656

¹⁵⁰ *Id.*

¹⁵¹ Documents providing the basis for the opinions contained in this Section are contained in Schedule 5 /Section C to this Report and its Subsections.

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organizations, and others. Research like this helps inform marketing strategy as to how to overcome obstacles to growing demand for a product.

3. The Distributors conducted strategic marketing planning for opioid manufacturers, helping them grow demand, and therefore, product sales over time.
4. The Distributors conducted direct marketing activities for the manufacturers, including advertising to their pharmacy customers; sending sales promotion offers (such as coupons and rebates) to pharmacies and patients; and assisting the manufacturers' personal selling efforts by training their sales people for them, hiring field sales reps, and staffing call centers. These direct marketing activities are key to increasing sales.
5. The Distributors also engaged in indirect marketing activities for the opioid manufacturers such as running behavioral compliance and medication adherence programs to ensure patients continued taking their prescribed opioids; offering continuing medical education programs to physicians and other healthcare professionals; hiring and training key opinion leaders and other spokespeople; and conducting clinical studies and authoring publications in medical journals. Each of these played an important role in elevating the market for prescription opioids. Moreover, the Distributors' own industry association, the Healthcare Distributors Alliance (HDA), played an important role in insuring unfettered access to opioid supply would continue, including government lobbying to ensure a favorable regulatory and legislative environment, as well as engaging media outreach to mitigate unfavorable press about the opioid crisis and to "turn the tide" of negative publicity into media coverage that was "more balanced."¹⁵²

1. Leveraging Retail Relationships to Market for Opioid Manufacturers.¹⁵³

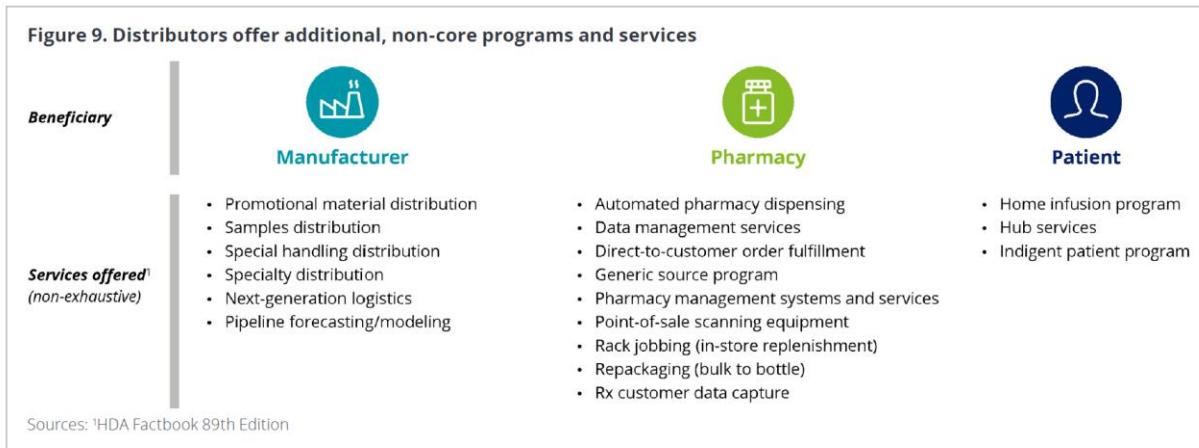
The Distributors industry association, the HDA, stated that Distributors performed a much broader role for pharmacies than simply getting product from the manufacturer to the pharmacies for dispensing (see Figure below).¹⁵⁴ Distributors offer franchising programs, consulting and technology services, and over-the-counter drugs and general merchandise products upon which many independent pharmacies depend to compete and effectively serve the communities in which they operate.¹⁵⁵

¹⁵² ABDCMDL00269293; ABDCMDL00269301

¹⁵³ Documents providing the basis for the opinions contained in this Section are contained in Schedule 5C-1.

¹⁵⁴ HDA, *The Role of Distributors in the US Health Care Industry* at 13.

¹⁵⁵ *Id.*



Cardinal Health’s “Solutions Guide” is a 54-page document that summarize these kinds of services the company provides to pharmacies that dispensed its opioid drugs, including advertising programs, trade magazines, competitive point of sale analysis, facilitation of discounts and rebates from manufacturers, and programs designed to strengthen the pharmacies’ relationships with their customers and increase customer “adherence” to taking their medication.¹⁵⁶ In 2010, *Chain Drug Review* (October 25, 2010), an industry trade magazine, featured Cardinal Health for its “menu of online services” offered through its Medicine Shoppe International (MSI) unit, including a digital advertising program to stream ads and educational content to LCD screens placed in retail pharmacies to target consumers while they wait for prescriptions to be filled.¹⁵⁷

Recall that **ABC** provides pharmacy management, staffing and additional consulting services, and supply management software to a variety of retail providers.¹⁵⁸ They offer trade magazines to pharmacists (Retail Remedy reaches 4000 pharmacists) and their patients (Health Connections reaches 135,000 GoodNeighbor pharmacy patients).¹⁵⁹

McKesson offered RelayHealth, billed as “the nation’s largest pharmacy network, improving delivery of and adherence to prescription medications.”¹⁶⁰ In addition, its “PriorAuthPlus” for retail pharmacies nationally automates prior authorization (PA) resubmissions to overturn denied claims; its denial conversion service monitors prescription claims denied as “product not covered;” its service enables patient to “leave the pharmacy with your brand without delay.”¹⁶¹

By offering value-added services to their pharmacy retail partners, the Distributors cemented their business relationships with these retail customers. Their deep competencies in understanding the pharmacists’ business needs; understanding the nuances of patients themselves (e.g., compliance with treatment); integration with respect to insurance and reimbursement; and supplying technology for better pharmacy management allowed the Distributors to become strategic business partners for the

¹⁵⁶ Document produced without a bates number.

¹⁵⁷ CAH_MDL2804_03225740

¹⁵⁸ AmerisourceBergen Form 10-K (2016).

¹⁵⁹ ABDCMDL00320055

¹⁶⁰ MCKMDL00724422

¹⁶¹ *Id.*

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pharmacies, serving as “trusted advisors” in their businesses. The more knowledgeable the distributor became about the pharmacists’ business, the greater the value they could provide in offering additional services. The greater the value, the stronger the relationship ties. The stronger the relationship ties, the less likely any particular pharmacist switches his or her business to a competing distributor.

One of the strongest ways to generate such “lock in” (in addition to providing excellent customer service) is through investments in technology. As noted previously, each Distributor each offered its own technology platform that tied the pharmacists to them.

In turn, the investments in technological platforms serving pharmacists generated additional value to the Distributors, allowing them to collect and harvest important information about the pharmacist’s behavior at the individual pharmacy level (orders volume, mix of orders, etc.).

The power of this data and the technology operated like a flywheel, generating continuous knowledge and insights around pharmacists’ needs and concerns, allowing Distributors to provide improved value-added services, further cementing the relationship. This technology and data-driven approach to channel relationships is imperative in today’s business environment.

Not only did all this data allow the Distributors to compete with each other; this specialized knowledge, customer data, understanding of and integration with customers’ business models, and established customer relationships made the Distributors valuable to the opioid manufacturers. The opioid manufacturers partnered with and relied on the Distributors for their insights and knowledge about the marketplace, and they used that knowledge to better target customers and grow the market.

2. Distributors provided market research services to pharmaceutical manufacturers¹⁶²

As outlined in Section II above, entitled “Marketing Basics,” market research is a critical component of designing a marketing strategy. Market research includes gathering both qualitative data (e.g., via focus groups or in-person meetings) and quantitative data (e.g., through surveys or third-party data sources), and analyzing the data to understand buying motivations and barriers, and to develop strategies to target the motivations and overcome the barriers to grow sales.

As part of their value-added services for the opioid manufacturers, the Distributors performed sophisticated market research on physicians, payers, pain specialists, patients, health care organizations, and pharmacists. The Evidence of these market research services appears in Schedule 5C-2.

For example, in 2000, McKesson’s Pharmaceutical Partners Group (MPPG) was contracted by Purdue to conduct focus groups at the upcoming American Academy of Family Physicians (AAFP) conference regarding physician attitudes about opioids. McKesson provided Purdue with the key conclusions and recommendations from its research, including:¹⁶³

#5: Family doctors are worried about long-term narcotics use and addiction; they are not comfortable prescribing high doses for patients who become tolerant: “Educating physicians about treatment strategies that reduce the risk of narcotic addition may help address

¹⁶² Documents providing the basis for the opinions contained in this Section are contained in Schedule 5C-2.

¹⁶³ PDD1701098050, PDD1701098054, PDD1701107091

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physicians' concerns; Purdue may want to consider sponsoring pain management conferences or lectures by opinion leaders to focus physician attention on addiction and tolerance issues.”

#9: Long-acting agents OxyContin and Duragesic are reserved for patients with acute pain prolonged over several days or weeks and for chronic pain. OxyContin does not suffer from the stigma of other narcotics such as morphine because it is long acting and doesn't produce euphoria. “Focusing on these issues in OxyContin marketing material may help increase its use and position it as a ‘safer’ narcotic alternative.”

#12: Few family doctors recall seeing clinical studies for opioid agents, including OxyContin; “several evince skepticism about such studies pointing out that, too often, these studies are sponsored by manufacturers of the drugs concerned.”¹⁶⁴

Research like this was done to help inform opioid marketing strategy as to how to overcome obstacles to growing demand for a product.

Similarly, in 2001, McKesson HBOC Pharmaceutical Partners Group (MPPG)/Market Research Division shared a quantitative pain study (dated November 2000) based on research it conducted at the American Academy of Family Physician's meeting Sept. 20-24, 2000 in Dallas TX, to identify features that are most appealing to doctors who regularly prescribe Duragesic and OxyContin.¹⁶⁵ After summarizing the findings, McKesson offers the following recommendations (p. 7): “The most obvious path to increase market share for Duragesic and OxyContin is to reduce cost, which is the primary barrier to prescribing either drug first-line.”¹⁶⁶ McKesson also suggested that Purdue consider a low-dose alternative to these two drugs to capture a larger market share among patients with mild-moderate pain; conduct additional research on non or low prescribers of Duragesic and OxyContin to understand what features are important when selecting pain meds.¹⁶⁷

In Fall 2001, McKesson Health Solutions held focus groups with a mix of pain specialists for Purdue; the focus groups were conducted during Purdue's Risk Management Advisory Boards meetings for the purpose of “OXU,” a new formulation later identified as Naloxone.¹⁶⁸ The key findings from this interim report, based on three of the four focus groups, suggested that anesthesiologists and primary care physicians would prescribe OXU (in lieu of OxyContin) to varying degrees. “The majority of primary care physicians envisaged prescribing OXU for most, if not all the patients for whom they currently prescribe OxyContin.”¹⁶⁹

McKesson also shared market research/ data with Purdue for its Butrans launch, showing “abandonment data” by price of co-pay for various meds; how to overcome denials through denial conversion and the increase in sales based on denial conversion.¹⁷⁰

Like McKesson, **AmerisourceBergen's Xcenda** unit was tasked with conducting market research and devising strategies based on that research. Xcenda performed such research and strategy for various opioid manufacturers. For example, in 2012, Xcenda performed research and provided an Executive

¹⁶⁴ *Id.*

¹⁶⁵ PDD1502117658

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ PDD1502100590

¹⁶⁹ *Id.*

¹⁷⁰ PPLPC030000564197

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Summary for Covidien on the key barriers for one of its new opioid drugs.¹⁷¹ Xcenda is hired to offer key insights and tactical recommendations, including signal testing to support recommendations, and to help Covidien decide which clinical studies will be most effective in creating a strong payer-focused value story supporting the launch of its new opioid drug. Xcenda worked closely with Covidien (by then Mallinckrodt), meeting to discuss research, strategy, and methodology.¹⁷² Xcenda then generated recommendations for positioning Mallinckrodt's new opioid product for favorable launch, including the following recommendations:¹⁷³

- undertaking 15 studies and publishing them;
- undertaking market research to test message language to communicate product value;
- involving medical affairs to publish key results;
- developing an AMCP (Academy of Managed Care Pharmacy) dossier;
- working to develop clinical pathways with Mayo Clinic; and
- developing a lecture series for physicians on pain management.

Similarly, Xcenda prepared an AMCP (Academy of Managed Care Pharmacy) dossier for Cephalon's (TEVA) Fentora opioid product in 2012.¹⁷⁴ Their later work (January 7, 2013) includes a Statement of Work for Fentora for a four-phase project (project team will include employees of both Xcenda and TEVA):¹⁷⁵

- Phase 1: kick off meeting with TEVA to initiate project, finalize target payer list
- Phase 2: develop list of target payers, timeline acquire and organize data
- Phase 3: run analysis to develop action plan for target plans
- Phase 4: validate the results via NAM WebEx

Xcenda went on to conduct segmentation analysis and analyze IMS data market share to guide the target health care plan list for Fentora.¹⁷⁶

Opioid manufacturers hired Xcenda repeatedly over time to provide this kind of market analysis to assist in guiding marketing strategy to grow demand. Xcenda worked with TEVA to prepare a value proposition for Vantrela,¹⁷⁷ to conduct primary research on payers, patients, and providers to "inform a meaningful and persuasive value proposition" (a "Triangulated Value Proposition") for Nucynta (a J&J product);¹⁷⁸ Xcenda also provided Market Access recommendations and a market comparator analysis for the Mallinckrodt team,¹⁷⁹ as well as a Budget Impact Model for Xartemis XR for Mallinckrodt, showing how market share would change over time based on particular market conditions.¹⁸⁰

¹⁷¹ MNK-T1_0001532952

¹⁷² MNK-T1_0001052415

¹⁷³ MNK-T1_0001052416

¹⁷⁴ TEVA_MDL_A_01236538

¹⁷⁵ TEVA_MDL_A_02553105

¹⁷⁶ TEVA_MDL_A_02819135; TEVA_MDL_A_02819133; TEVA_MDL_A_02953959

¹⁷⁷ TEVA_MDL_A_09165501; TEVA_MDL_A_03547843

¹⁷⁸ JAN-MS-00817084

¹⁷⁹ MNK-T1_0000641574

¹⁸⁰ MNK-T1_0002191219

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Its July 2014 work for Mallinckrodt on Xartemis XR noted the importance of physician acceptance and “published literature in peer-reviewed journals as the most credible source of data.”¹⁸¹ As my report later shows, Xcenda performed and published these studies. Xcenda’s report for Mallinckrodt also noted that deterrent characteristics in opioid therapies do not have an impact on clinical/coverage decision making and hence, human abuse liabilities studies were considered “nice to have” rather than “must have” data.¹⁸²

3. Distributors developed marketing strategy (segmentation, value proposition/differentiation, product positioning, etc.) for opioid manufacturers.¹⁸³

In addition to the market research the Distributors conducted on behalf of the opioid manufacturers to guide the development of the manufacturers’ marketing strategy, the Distributors often did the actual strategic marketing planning for opioid manufacturers. Recall from Section B, Marketing Basics, that companies develop marketing strategy to guide strategic priorities and resource allocations to grow product sales. Marketing strategy is based on a systematic process of identifying strengths, weaknesses, opportunities and threats in a marketplace (sometimes referred to as a SWOT analysis); segmenting markets; honing their focus on key target markets; crafting value propositions that resonate with targeted customers; implementing the marketing strategy; and then evaluating the results/return-on-investment of that strategy on an ongoing basis.

McKesson prepared a marketing plan for Actavis stating the “primary goal is to move market share of Actavis’ oxymorphone ER tablets within McKesson Pharmaceutical’s OneStop customer base;”¹⁸⁴ awareness would be achieved through direct promotion to McKesson’s customers. McKesson developed a marketing plan for TEVA to educate pharmacists regarding new REMS [Risk Evaluation & Mitigation Strategies) requirements for ACTIQ and Fentora.¹⁸⁵ McKesson Manufacturer Marketing prepared a plan for Purdue to “create pharmacist awareness & education of RxPatrol (pharmacy security).”¹⁸⁶

ABC’s Xcenda performed all these aspects of marketing strategy for the opioid manufacturers. Purdue relied on AmerisourceBergen’s (ABC’s) Xcenda unit for strategic assistance. A series of emails from October 2-8, 2014 discussed the upcoming Purdue October 2014 HYD Advisory Board, including an attendee list, a draft agenda, and target advisory board dates as well as action items for Xcenda and for Purdue.¹⁸⁷ These Advisory Boards played a critical role in giving legitimacy to the pharma companies’ strategies. The fact that the Distributors helped to plan and manage these Advisory Board meetings speaks to their critical role as a partner in the manufacturer’s efforts.

Xcenda similarly provided strategic analysis for TEVA on opioid product Fentora (October 2012), including its savings program, sales force metrics, competitive intelligence, patients, market access (percent of sales by channel, e.g., Medicaid, Medicare, third-party payer, cash), and marketing channels (call centers, mails, web banners, etc.).¹⁸⁸

¹⁸¹ MNK-T1_0005053502

¹⁸² *Id.*

¹⁸³ Documents providing the basis for the opinions contained in this Section are contained in Schedule 5C-3.

¹⁸⁴ ACTAVIS0622787

¹⁸⁵ TEVA_MDL_A_12746422; MCKMDL00353374

¹⁸⁶ MCKMDL00353316

¹⁸⁷ PPLPC046000062722; PPLPC046000062729; PPLPC046000062731; PPLPC047000031685

¹⁸⁸ TEVA_MDL_A_02964576

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In 2013, ABC's Xcenda unit conducted a pain management landscape assessment for TEVA,¹⁸⁹ including preparation of an agenda and materials for TEVA's upcoming Chronic Pain Management Payer Advisory Board meeting.¹⁹⁰ The objectives include: understand current management of pain, identify payers' unmet needs in pain treatment, ascertain perceptions on the level of concern of opioid abuse, understand payers' perspectives on the importance of meds, discuss resources for decision making, discuss clinical, health, economic outcome research.¹⁹¹ Relatedly, there was a similar project for the Hydrocodone Payer Board Meeting.¹⁹²

J&J also engaged Xcenda to provide marketing strategy for its opioid products, including strategic planning for 2008 Tapentadol Outcomes,¹⁹³ research on how to navigate Part D Exceptions and prior authorizations (PA) needed for Nucynta (2012);¹⁹⁴ a Long-Term Care Reimbursement Training Deck;¹⁹⁵ the creation of an "FST tool" (Field Sales Tool—a type of app) for all 25 health care plans to provide information to providers on how to navigate Medicare Part D Exceptions and Prior Authorizations.¹⁹⁶ The exception to the Medicare plan "is critical to ensure patient access."¹⁹⁷

4. Distributors conduct direct marketing of opioid products.¹⁹⁸

As outlined above in Section IV, in an integrated supply chain, all parties act in harmony to maximize profitability for all entities. To achieve this level of coordination, Distributors provide value-added services to both upstream suppliers and downstream customers, integrating the industry's marketing efforts so all parties collectively benefit.

Among the direct marketing services the Distributors provided to opioid manufacturers (on both a fee-for-service basis as well as based on the sales lift generated by the marketing activities the Distributors performed) were:

- i. Advertising to pharmacists to create awareness of the opioid products;
- ii. Sales promotion strategies including offering vouchers to actual patients (through pharmacists) for free pills; rebates to pharmacists for each bottle of opioids orders; and
- iii. Personal selling and sales support/training.

These marketing services were directed not only to pharmacies, but also to physicians, patients, payers, pain management providers, and other health professionals (nursing staff, administrators, medical directors).

i. Advertising services on behalf of the pharmaceutical manufacturers: Leveraging distributors' technology platforms to advertise to pharmacists

¹⁸⁹ TEVA_MDL_A_00858252

¹⁹⁰ TEVA_MDL_A_00858261

¹⁹¹ TEVA_MDL_A_00858300; TEVA_MDL_A_00858301

¹⁹² TEVA_MDL_A_00858307; TEVA_MDL_A_00858312; TEVA_MDL_A_02955356

¹⁹³ JAN-MS-00447221

¹⁹⁴ JAN-MS-00364683; JAN-MS-00364686; JAN-MS-00364689

¹⁹⁵ JAN-MS-00362395

¹⁹⁶ JAN-MS-00362392; JAN-MS-00866310; JAN-MS-04227457; JAN-MS-04216373

¹⁹⁷ JAN-MS-04218103

¹⁹⁸ Documents providing the basis for the opinions contained in this Section are contained in Schedule 5C-4(a).

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Creating awareness of and educating customers about products is a critical function of marketing, and it is designed to create demand for those products. Each of the Distributors was integrally involved in the advertisement and promotion of opioid products to their retail chain pharmacy customers through various channels including email blasts, banner advertising, direct mail, digital signage, weekly newsletter content and telemarketing. The Distributors were key partners in opioid advertising designed to grow demand from pharmacies. By leveraging the Distributors' technology platforms, manufacturers could reach thousands of the Distributors' existing pharmacy customers in a single email blast. Further, running banner ads for opioid drugs on the Distributors' websites, where pharmacies go to place orders, ensures advertising placement in front of the targeted customers.

Cardinal Health's advertising programs included running awareness and education campaigns for the pharma manufacturers through its eConnection email marketing; ads in its weekly publications to chain pharmacies (CVS, Walgreens); direct mail specifically targeted to pharmacists who had ordered competitors' product in the past three months, and digital signage on its Pharmacy Health Network that reached actual consumers at retail pharmacies.¹⁹⁹

McKesson's advertising programs (often referred to as Manufacturer Marketing Product Promotional Agreements) included telemarketing (calls made directly to pharmacists on the manufacturer's behalf);²⁰⁰ DirectRX advertising on its online platform McKesson Connect;²⁰¹ fax blasts; RX Mail (direct mail to both McKesson's Health Mart pharmacists as well as independent pharmacies); RX Bulletin (HTML email message); RX Focus.²⁰² These ads could be targeted to specific pharmacists based on their past orders of competitive products, size of orders, or state/territory.²⁰³ The ads also included "discounts to pharmacists to incentivize them."²⁰⁴

McKesson also offered its pharmacists an "auto ship" program.²⁰⁵ For example, in one case, 3,001 pharmacists who were categorized as "high dispensers of similar medications" received auto shipments of one four-count carton of Butrans the week that it launched.²⁰⁶

The Distributors also provided data to the manufacturers regarding how many impressions the campaigns delivered (e.g., the number of times the ad appeared in front of customers), the number of inquiries the ads generated, and the product lift due to the ads.²⁰⁷

AmerisourceBergens' advertising programs provided to the manufacturers included online education, customer acquisition and promotion through myGNP pharmacy sites, including ads on myGNP.com,

¹⁹⁹ ACTAVIS0600353; PPLPC004000298375; MNK-T1_0000823151; ACTAVIS0220239; ENDO-CHI_LIT-00294169; ENDO-CHI_LIT-00431191; CAH_MDL2804_00133350; TEVA_MDL_A_13494044; CAH_MDL2804_00132726

²⁰⁰ PKY180416642

²⁰¹ MCKMDL00353305; MCKMDL00706767; PPLPC004000245474; ACTAVIS0622787

²⁰² TEVA_MDL_A_12746422; MCKMDL00353374; MCKMDL00353316; MCKMDL00353261; MNK-T1_0006909534; MCKMDL00353277

²⁰³ MCKMDL00353282

²⁰⁴ ALLERGAN_MDL_00684866

²⁰⁵ MCKMDL00353279

²⁰⁶ MCKMDL00490713

²⁰⁷ MNK-T1_0000990815; MCKMDL00353307

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direct mail, fax blasts, Web banners on ABC's PassPort (also known as ABC Order-- the ABC ordering platform), Affiliate Links (e.g., placing a link to the manufacturer's content on manufacturer-sponsored "channels"), ad inserts in its monthly magazine for pharmacists, *Retail Remedy*, email through its CustomConnect campaign service, and ads on "The Link." "The Link" is its customer communication portal used to "reach and message pharmacy customers" and "educate pharmacies about [manufacturers'] suite of products." These ads included "supplier spotlight" banners that ABC sold to manufacturers as a monthly ad service.²⁰⁸ As an example, ABC sent a fax blast to 1700 pharmacists for Purdue's Butrans for [REDACTED].²⁰⁹ ABDC also used its online platforms to offer various "channels" (e.g., a Pain Management Channel) where the manufacturers were featured as "sponsors" (for a fee: [REDACTED]/month). In addition to the sponsorship fee [REDACTED], ABDC was also compensated for each visitor it funneled to the channel who registered with the site to continue to receive information.²¹⁰

Evidence indicates that the manufacturers relied on the Distributors to perform marketing on their behalf to avoid legal scrutiny. For example, in the communication about the "most effective ways (for ABDC) to get information to ABDC's customers about new sizes of OxyContin and rebate information," the emails between ABDC and Purdue note that Purdue cannot do a cover letter for the mailing "without going through legal which will take weeks, so it would be better if ABDC did that."²¹¹

ii. Sales promotion programs (offering coupons and rebates to customers) for opioid drugs

In addition to leveraging the technology platforms and communication channels in their established relationships with pharmacies to send advertising on the opioid manufacturers' behalf, the Distributors also used them to implement the opioid manufacturers' sales promotion offers to downstream customers.

As outlined above in Section II, Marketing Basics, sales promotions are incentives to customers to encourage them to "buy now," such as coupons and rebates. Given that these promotional tactics are both time-limited in nature and offer a financial deal, they are highly effective in generating sales lift on the promoted products.

Given their effectiveness, the use of sales promotions often puts the financial gain of the business at odds with what is right for the consumer. Instead of focusing on what is right for the patient, sales promotion puts the focus on the financial gain pharmacies will receive from these products.

As part of their fee-for-service marketing programs, **McKesson** offered "voucher" programs on behalf of the opioid manufacturers to actual patients. In one case, the voucher was for three free pills. Given the expected 5% redemption rate of the vouchers,²¹² the email from McKesson states, "This will be a great

²⁰⁸ PPLPC051000001178; ABDCMDL00002141; ABDCMDL00002632; PPLPC022000986875; ABDCMDL00002126; ABDC_INCID0000189, ABDMDL00002828; ABDCMDL00002128

²⁰⁹ PPLPC004000256865

²¹⁰ PPLPC051000001178

²¹¹ PPLPC004000142842

²¹² A typical redemption rate for coupons at retail is 1-2%

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way to add some PUNCH to your launch and offer true differentiation.”²¹³ In another case, the offer was for 10 free pills for Nucynta.²¹⁴

McKesson also offered coupons for copay assistance to make brands more affordable for more patients. Its program for Nucynta ER included a \$25 co-pay savings program that yielded an increase of 180% in average monthly claims over prior years’ claims; a 95% overall retention rate (compared to higher copays). In February 2011, McKesson prepared an RFP for to administer savings card programs for J&J’s opioid drug, Nucynta ER.²¹⁵ Among the compelling reasons McKesson communicates in the proposal for why J&J should partner with them are that “over the years, we’ve become a fluid extension of the J&J team rather than just a vendor” (p. 10) and McKesson’s expertise in health behavior change and consumer marketing (based on patient enrollment, profiling, and other data) provides its brand partners with communication, promotion and distribution options (p. 12).

McKesson offered similar voucher promotions for Actavis (Kadian)²¹⁶ and Janssen.²¹⁷

McKesson also offered a RelayHealth LoyaltyScript Platform,²¹⁸ described as intelligent prescription couponing, to address prescription nonfulfillment due to medication costs, with the value proposition to the manufacturer, “More Rx’s processed!²¹⁹

The promotions included “financial incentives” to pharmacies as well, such as rebates of \$25 for each bottle of Oxymorphone sold. In this case, the opioid manufacturer also incentivized the Distributor, with an additional \$10/bottle paid to McKesson. McKesson could also earn 5x or 6x more than that for “proof of retailer stocking” the brand.²²⁰

Like McKesson, **Cardinal Health** offered a savings cards for opioid drugs.²²¹

The role of the Distributors in running sales promotion strategies for the opioid manufacturers is problematic and troubling. In using incentives to get pharmacies to stock more and get patients to buy more, they were promoting opioids as if they were not highly addictive products.

Internally, the Distributors recognized they were engaged in improper marketing activities but that sales must go on no matter what the risk. For example, an email thread regarding special dating and a buy-in on OxyCodone expressed concern about using these marketing techniques with a controlled substance.²²² The response from other colleagues within McKesson was that “this is standard promotion for stocking the product, rebates based on purchases. If there is something we are not supposed to do, this is the first I’m hearing about it” (Greg Yonko). Don Walker (who had expressed

²¹³ JAN-MS-01136836

²¹⁴ JAN-MS-01071368

²¹⁵ JAN-MS-00864519; JAN-MS-00865180

²¹⁶ ALLERGAN_MDL_02495818

²¹⁷ JAN-MS-00785242

²¹⁸ PPLP003361649; PPLP003361918

²¹⁹ PPLPC022000184774

²²⁰ ACTAVIS0623776

²²¹ PPLPC004000298375

²²² MCKMDL00543462

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concern) replied: "Easy big fella. ... we do need to think through how we handle promos on controls, especially Lifestyle drugs like Oxycodone."²²³

Another internal McKesson email thread regarding its OneStop Generics Campaign on lower-priced Oxycodone targeted to customers with purchase history of Mallinckrodt Oxycodone states, "Are you kidding me!! We are auto shipping oxy!!!"²²⁴ This concern escalated, with the next person asking "What's going on? Surely we are not promoting Oxy on special."²²⁵ The thread concludes with Don Walker justifying the problematic strategy by responding, "We agreed to offer the lower price but are not changing any thresholds."²²⁶

iii. Field Sales Support Systems²²⁷

As Section II. Basic Marketing explains, another critical marketing function is sales/personal selling. Personal selling is conducted both in-person (e.g., when one of the Distributors' sales people visits pharmacists) as well as through remote sales (e.g., through call centers that both staff 800# for inbound calls as well as engage in outbound telemarketing). As part of their fee-for-service marketing for the manufacturers, the Distributors also provided field support via staffing call centers to work with not only pharmacists, but patients, health professionals, and payers as well. Evidence for this appears in Schedule 5.4 (c).

The Distributors cannot say they were not engaged in marketing when they provided the training for opioid manufacturers' sales forces on how to talk to physicians and other health care professionals. Indeed, evidence shows that the Distributors provided direct training to the opioid manufacturers' sales forces (detailers) who called on physicians. For example, ABDC's Xcenda's slogan for this services states, "*We become extensions of the sales force*" (emphasis added).²²⁸

As part of their role in training the manufacturers' sales representatives, the Distributors provided messaging and talking points for the opioid manufacturers' detail teams. One slide deck used for the training offered detailed role plays to help sales reps handle challenging questions.²²⁹ A different training deck included specific talking points for J&J's sales representatives when talking to key target markets including the Director of Nursing, Consultant Pharmacist, Administrator, and Medical Director. It also includes details on how to manage the Exceptions/Appeal/PA process.²³⁰

ABDC's Xcenda unit also hired field-based payer coverage specialists (FCS) to support ENDO's pain products; to support regional needs of ENDO's sales force and their customers in payer policies for prior authorization; and to provide education to support patient access.²³¹ The field specialists that Xcenda

²²³ *Id.*

²²⁴ MCKMDL00539021

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ Evidence for this section can be found in Schedule 5.4 (c).

²²⁸ JAN-MS-00814133

²²⁹ JAN-MS-00814133

²³⁰ JAN-MS-04227313

²³¹ ENDO_OPIOID_MDL-04815436

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hired would not only make in-person customer visits, but would also make phone calls and host teleconferences.

ABDC's Lash Group (offering consulting services to the pharma manufacturers) proposed to hire 2600 associates at five call centers to support Teva's core areas, including pain management, serving 8 million patients.²³² The Lash Group also staffed a call center with "health professionals who will offer product-related information to physicians and patients" for Purdue.²³³

5. Distributors Conducted Indirect Marketing of Opioid Products.

As detailed in Section II above, in addition to direct (e.g., branded) marketing, marketing also includes sophisticated indirect strategies that are designed to influence customers' and other stakeholders' perceptions of the industry and product category. The goal of these strategies is to enhance customer attitudes about products to elevate the market and grow sales. This was especially true with prescription opioids, where attitudes of the medical and pharmacy communities towards opioids had been negative and emphasized conservative use. Therefore, opioid manufacturers engaged the Distributors to assist in a number of indirect marketing activities designed to allay the concerns about the widespread use of opioids in the medical and pharmacy communities, including:

- i. Training in behavioral coaching techniques to ensure patient compliance with prescribed medications.
- ii. Offering continuing education programs for physicians, pharmacists and healthcare providers promoting the widespread use of opioids.
- iii. Hiring and training key opinion leaders (speaker series) to promote the widespread use of opioids.
- iv. Creating/funding clinical trials and publications with the purpose of influencing physician attitudes towards broader opioid prescribing.
- v. Working through the industry trade associations to ensure favorable operating conditions and promoting the widespread use of opioids.

Recall from Section III that there is a heightened duty of care when using these indirect marketing strategies. These activities are both more subtle and more insidious, in the sense that customers and other stakeholders do not realize these tactics are paid marketing activities, and so their "filters" to skeptically view such messages are absent. Therefore, the FTC requires that these paid influencers clearly disclose their relationship with the company. Further, when these indirect tools are used for potentially dangerous products, they run greater risks of causing problems. The Distributors have not exhibited this heightened duty of care when they partnered with the opioid manufacturers to drive demand through indirect marketing.

i. Distributors ran patient "adherence" programs²³⁴

Each of the Distributors drove demand through influencing patient behavior, including the use of programs to ensure opioid users "adhered" to taking their opioid medication and that patients had

²³² TEVA_MDL_A_11786072

²³³ PPLPCO31001481881

²³⁴ See Schedule 5.5 (a).

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"access" to opioids. These efforts ensure patients keep using opioids so the sales stream would continue. The Evidence for the patient adherence programs appears in Schedule 5.5 (a).

AmerisourceBergen drove patient demand in this way through its subsidiary, Lash Group. Through this subsidiary, they contracted with opioid manufacturers to provide programs for patient medication "adherence" and "patient access."²³⁵ Its proposal to Teva promises to "enhance the success of pharmaceutical brands by ... driving adherence."²³⁶ In 2016, for example, Lash contracted with Purdue Pharma to promote and "facilitate access" to the opioid Hysingla by establishing a call center that served as the "main point of contact for all inquiries, service requests and outbound calls related to the Product."²³⁷ In this way, Lash's programs contributed to the increased use of opioids.

Cardinal Health likewise offered comprehensive patient adherence services through an "Access & Patient Support" program, promising "compliance and persistency" when "patients don't take their medications as directed."²³⁸ This includes placing outbound calls to patients, as well as answering questions and providing other support. Cardinal's patient adherence programs drive the demand for opioids and other drugs.

McKesson offered a manufacturer-sponsored Pharmacy Intervention Program ("PIP"), which trains pharmacists on how to provide "coaching sessions" to patients. Identified as "a patient adherence program from the McKesson Sponsored Clinical Services Network," McKesson marketed PIP to drive sales for all players in the integrated supply chain: the manufacturer, the pharmacy, and of course McKesson itself. Marketed to the manufacturers as a program to "reduce discontinuations and improve patient adherence,"²³⁹ PIP offers an opportunity to address patient needs by uncovering motivations and coaching them to adhere to the prescribed regime.²⁴⁰ McKesson incentivized the pharmacies to participate, paying pharmacists for every completed intervention and then invoicing the manufacturer for the costs. McKesson not only trained pharmacists to increase opioid sales; it also conducted "behavioral call campaigns" directly to patients. McKesson's call center staff, trained in behavioral coaching techniques, would contact patients directly by telephone to ensure that patients took their medications, including opioid products.²⁴¹ McKesson claimed its program "takes adherence to a new level through combined behavioral expertise, call center resources, and measurement."²⁴² McKesson states that its "Patient Reinforcement Program" results in a 440% increase in conversion rates for patients, conveying the extremely high impact of this program on sales.²⁴³ (This same presentation notes that health care professionals re-initiating opioid experienced patients "inappropriately dosed them on

²³⁵ See e.g. ABDCMDL00323380 (p. 31) (Amerisource business summary of Lash Group's patient adherence services).

²³⁶ TEVA_MDL_A_11786072

²³⁷ PPLPC031001481881

²³⁸ <https://www.cardinalhealth.com/en/services/manufacturer/biopharmaceutical/patient-access-and-adherence/patient-adherence-solutions.html>

²³⁹ PPLPC002000140782; PPLP003299959; PPLP003337352; PPLPC028000587023

²⁴⁰ PPLPC004000248015

²⁴¹ MCKMDL00493101; MCKMDL00496195; MCK-AGMS-069-0002523; MCKMDL00726854

²⁴² MCKMDL00726854

²⁴³ JAN-MS-01130535

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the 5 mcg/hour when they should be initiated on the 10 mcg/hour,” also a way to increase opioid use.²⁴⁴⁾

The importance of this Pharmacy Intervention Program was highlighted in an internal Purdue memo informing the field sales people about the launch of McKesson’s Pharmacy Intervention Program for a Butrans Adherence Program that includes face-to-face coaching sessions to overcome adherence barriers to “prescribed medication therapy.”²⁴⁵

McKesson also provided a “Denial Conversion Program”²⁴⁶ designed to increase patient adherence to prescribed medications via an automated process on rejected prescriptions. For instance, if a prescription is rejected by insurance as non-reimbursable, RelayHealth’s Denial Conversion solution converts the rejected claim to a paid response and returns the specified patient co-pay and patient savings notification. The prescription drug gets dispensed as prescribed, aiding in patient medication adherence. McKesson’s marketing material refers to this as an “integrated engagement” system to create “behavior changing brand experiences.”²⁴⁷

ii. Distributors offered continuing education to healthcare providers and pharmacists designed to increase opioid demand.²⁴⁸

As noted in Section II, continuing education (CE) initiatives are often part of a company’s content marketing (thought leadership). In content marketing, the company offers continuing education programming that is aligned with its broader marketing thrust, and thereby, creates demand for its products and services. The Distributors’ value-added “continuing education” services also extended to patient relationship solutions, and outreach to physicians and nurses. The documentation for the evidence in this section appears in Schedule 5.4 (b).

ABC Specialty Group, Xcenda, offered several such educational initiatives designed to promote the widespread use of opioids. Titled “Knowledgedriven,”²⁴⁹ its provider reimbursement services (PRS)/ Pain Policy Educational Initiative provides over 1,300 educational programs each year (teleconference or live), partnering with manufacturers to navigate barriers for patient access to important therapies, proclaiming “We become change agents for improved access to healthcare.”²⁵⁰ Xcenda details the various audiences who would use these education services, including sales force, physicians, nurses, residents, pharmacists, patient advocates, practice managers, and more. The tools they offer include tip sheets; brochures; helpful hints; dinner, lunch, breakfast programs; and newsletters for providers, patients, and sales reps. At these events, Xcenda would allow the pharmaceutical manufacturer’s detail team recruit providers to attend as their guests. Xcenda states that the return on investment (ROI) for these educational services includes: ensuring that the “client” (e.g., the pharma manufacturer) is perceived by the various audiences as bringing value added products to market; increasing patient access and appropriate prescribing behaviors; increasing awareness, exposure, and utilization of “Drug

²⁴⁴ *Id.*

²⁴⁵ PPLP003451464;

²⁴⁶ PPLPC030000564197

²⁴⁷ JAN-MS-00814133

²⁴⁸ See Schedule 5.5 (b)

²⁴⁹ JAN-MS-00814133

²⁵⁰ *Id.*

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X" following the program due to better understanding (say, of reimbursement); and penetrating markets that were off limits previously. These educational programs include "facts" to address fears of causing addictive behaviors (e.g., "Debunking the Myth" on controlled substances).²⁵¹ Xcenda also offered a healthcare provider "opiophobia" speaker/education initiative.²⁵²

Other continuing medical education was provided by **ABC's Imedex** unit. As noted previously, Imedex is an accredited provider of physician continuing medical education that support manufacturers and healthcare providers along the pharmaceutical supply channel.²⁵³ Schedule 5.5 (b)/Imedex includes evidence of the many ways this group provided Continuing Education for the pharma manufacturers, much of it focused on expanding the use of opioids in pain management. By normalizing the use of opioids in pain management, this type of indirect marketing played an important role in elevating the market, allaying physician concerns about the risks of opioids and increasing demand.

Similarly, **McKesson** also offered CE courses. For example, it offered a Pain Management CE course for pharmacists at its McKesson Trade show that was paid for by a "grant" from Purdue.²⁵⁴ Other CE programs included: "The Role of the Pharmacist in Medication Management of Chronic Pain" and "Controlled Substance Prescriptions and Pain Management."²⁵⁵

Purdue also relied on distributors to field its continuing education seminars, both through locating seemingly impartial speakers and through funding.²⁵⁶

Similarly, **Cardinal Health** offered "Controlled Substance Prescriptions and Pain Management" Continuing Education program at its Cardinal Health Show, its trade show for industry professionals. It also offered Continuing Education courses at its annual Retail Business Conference.²⁵⁷

iii. Hiring and training key opinion leaders to promote the widespread use of opioids²⁵⁸

Section II above describes that marketing often relies on using expert spokespeople to harness the credibility and expertise these spokespeople to indirectly "burnish" their products' image through a halo (carryover) effect. This marketing tactic can be quite powerful in that it bypasses the usual skepticism customers have with traditional marketing tactics. In the case of opioid marketing, these spokespeople were referred to as Key Opinion Leaders (KOLs).

²⁵¹ *Id.*

²⁵² JAN-MS-00326339; JAN-MS-00326341

²⁵³ Even before Imedex was owned by ABDC, it played an important role for the pharmaceutical manufacturers. For example, in 1997, Purdue sponsored a Pain Management and Chemical Dependency Conference (a session on opioid therapy for chronic non-malignant pain) that was run by Imedex. See PKY180947495, PKY180796666.

²⁵⁴ PPLPC008000022314

²⁵⁵ PPLPC004000122279

²⁵⁶ PPLPC004000183541

²⁵⁷ PPLPC008000036382

²⁵⁸ See Schedule 5.5 (c)

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Recall that the FTC requires that paid sponsors identify themselves.²⁵⁹ Moreover, industry codes of conduct require paid sponsors be open about their relationship with the company.²⁶⁰ In the case of potentially dangerous products, these standards are imperative to mitigate potential harms.

At least one Distributor, ABDC, not only recruited key opinion leaders (KOLs) on behalf of opioid manufacturers, but hired them to keep the names off the manufacturer's books to obfuscate the KOL's role.²⁶¹

The Distributors also trained these KOL's for their engagements. These techniques were used to bolster the perception of safety and credibility of opioids in the marketplace, contributing to demands and sales for all industry players.

In its BUTRANS Managed Care Advisory Board Weekly Status for Purdue, Xcenda describes its KOL (presumably Key Opinion Leader) training program that includes messaging for new pain products and training speakers for MCO plans (presumably Managed Care Organizations).²⁶²

iv. Distributors Role in Conducting Clinical Trials and Writing Journal Publications²⁶³

Another aspect of indirect marketing/thought leadership includes developing white papers and other publications that establish the credibility and authenticity of the company and its products. In their role in both developing marketing strategy and implementing those strategies in support of the manufacturer's marketing efforts, the Distributors' market research (previously summarized in Section VI C (2) identified the importance of clinical trials and publications in medical journals. The Distributors then (jointly with the pharmaceutical manufacturers) performed these studies with the purpose of influencing physician attitudes and prescribing behavior. Again, the integrated supply chain was working to elevate sales and grow demand for the industry, to the benefit of all players.

ABDC's Xcenda provides the best illustration of the Distributors' role in identifying, conducting, and writing studies that were later published in the journals, with Xcenda's personnel listed as co-authors, as illustrated in the Table below. Listed in the Table are a sample of studies that Xcenda helped to conduct, write, and publish. For example, for a study on how opioid users were affected by alcohol abuse, Xcenda developed the study's design, statistics, timeline, and objectives.²⁶⁴ TEVA sponsored the study, which was then presented at medical conferences²⁶⁵ and later published (see the 2015 and 2017 TEVA alcohol studies in the Table below with Xcenda personnel as co-authors below).

Year	Journal/Title/Author Affiliations
2010	<i>The American Journal of Pharmacy Benefits</i> “Review of outcomes Associated with Formulary Restrictions: Focus on Step Therapy”

²⁵⁹ FTC, *Disclosures 101 for Social Media Influencers*, (November 2019). (Available at <https://www.ftc.gov/tips-advice/business-center/guidance/disclosures-101-social-media-influencers>).

²⁶⁰ See The Code of Ethics for the Public Relations Society of America (Schedule 4)

²⁶¹ PPLPC004000183541

²⁶² PPLPC024000532502; PLPC024000532503; PPLPC039000672710

²⁶³ See Schedule 5.5 (d).

²⁶⁴ TEVA_MDL_A_02366621

²⁶⁵ TEVA_MDL_A_03217417

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	Authors from Xcenda & Novartis; Funded by Novartis
2010	<i>Current Medical Research and Opinion</i> “Adverse event profile of tramadol in recent clinical studies of chronic osteoarthritis pain” Funded by Ortho-McNeil Janssen Scientific Affairs; Author a consultant to J&J; employees of J&J; Xcenda employee and J&J consultant
2014	<i>Journal of Managed Care Spec. Pharm.</i> “Development and Validation of a Risk Score to Identify Patients at High Risk for Opioid-Related Adverse Drug Events.” Authors from Xcenda and funded by Pacira Pharmaceuticals
2014	<i>American Journal of Health-System Pharmacy</i> “Adverse drug events among patients receiving post-surgical opioids in a large health system: Risk factors and outcomes” co-author from Xcenda
2015	<i>Journal of Pain</i> “Long-term opioid users with chronic non-cancer pain: differences between patients with and without diagnosed alcohol abuse or dependence” Authors same as above (Xcenda & TEVA) Funded by TEVA
2017	<i>Adv. Ther.</i> “Hospitalization Costs Acetaminophen Plus Other IV Analgesics or IV Opioid Monotherapy” Funded by Mallinckrodt; Authors from Xcenda and Mallinckrodt's HEOR Dept. (Health Economics & Outcomes Research)
2017	Article published by Dovepress “Health care resource use and cost differences by opioid therapy type among chronic noncancer pain patients” Authors at Xcenda and Teva
2017	<i>Journal of Managed Care & Specialty Pharmacy (JMCP)</i> “Burden of Alcohol Abuse or Dependence Among Long-Term Opioid Users with Chronic Noncancer Pain.” Authors at Xcenda and TEVA Funded by Teva
2018	<i>Journal of Opioid Management</i> “Long-term opioid users with chronic noncancer pain: Assessment of opioid abuse risk and relationship with healthcare resource use” Authors at Xcenda and TEVA Funded by Teva (see TEVA_MDL_A_08855370)
2019	<i>Journal of Pain & Palliative Care Pharmacotherapy</i> . “Opioid-related respiratory and gastrointestinal adverse events in patients with acute postoperative pain: prevalence, predictors, and burden” Sponsored/funded by Trevena.
2020	<i>Cephalalgia Reports</i> “Treatment Patterns of Patients Diagnosed with Major Headache Disorders: a retrospective claims analysis.” Funded by Promius Pharma; Authors from Xcenda and “Real-World Evidence” Xcenda;

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McKesson also identified the important role of clinical trials. Its “Butrans Commercial Strategy/ Brainstorm session 2” for Purdue acknowledged that failed clinical trials were a problem, with a need to publish review articles to address this.²⁶⁶

The conflict of interest inherent in the cozy relationships among members of the pharmaceutical industry/supply chain and the journals is concerning. After an article in *JAMA Oncology* highlighted the potential conflicts of interest, AmerisourceBergen felt the article was potentially damaging enough that it commented on the article in its Sept. 9, 2016 issue of its publication *Health Policy Weekly*.²⁶⁷ After rebutting the calculations in the *JAMA* article, they offered a different conclusion: “Transparency of financial conflicts of interest is important, but the issue is complex, and a balanced perspective is needed.”²⁶⁸ Additionally, the United States Senate Financial Committee investigated the opioid industry’s financial ties to front groups and indirect marketing and found the opioid industry behind a lot of seemingly impartial groups.²⁶⁹

These conflicts also existed with medical journals themselves. For example, Melissa McCart, Xcenda’s Director of Global Health Economics & Outcomes Research (HEOR) was named editor at *The Journal of Managed Care & Specialty Pharmacy*, on December 18, 2018.

v. Working through the industry trade associations to ensure favorable operating conditions and combatting media and government pushback against opioids.²⁷⁰

Recall from Section II that industry trade associations play an important role in marketing to elevate the industry. These trade associations serve the interests of its members and perform key functions that would be costly or less impactful were each individual member to perform that function on its own. Among these common functions that trade associations perform are government lobbying, media relations, and other communications and advocacy services. By working behind-the-scenes to influence favorable media coverage and government relations, the industry trade association bolsters the ability of the integrated supply chain to market and sell its products successfully.

The opioid Distributors’ indirect marketing efforts also included working through its trade association, the Healthcare Distributor Alliance (previously the Healthcare Distribution Management Association) to ensure favorable operating conditions for the industry.

The HDA (originally the National Wholesale Druggists’ Association, and later the Healthcare Distribution Management Association) “represents primary pharmaceutical distributors. One of its fact sheets highlights the Distributors’ role in “delivering solutions nationwide” and its strategic role as a supply

²⁶⁶ PPLPC030000564197

²⁶⁷ Aaron P. Mitchell, Ethan M. Basch, Stacie B. Dusetzina, Financial Relationships With Industry Among National Comprehensive Cancer Network Guideline Authors, *JAMA Oncology*, December 2016.

<https://jamanetwork.com/journals/jamaoncology/fullarticle/2546172>

²⁶⁸ XCENDA BEHIND THE SCENES: *JAMA*: Diving Into the Deep End of Financial Conflicts of Interest, *Health Policy Weekly*, Sept. 9, 2016, at

<https://marketing.xcenda.com/acton/fs/blocks/showLandingPage/a/4930/p/p-0136/t/page/fm/0>

²⁶⁹ <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf>

²⁷⁰ See Schedule 5.5 (e).

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chain leader and convener in advocacy and education.”²⁷¹ Its website further states that “distributors do far more than manage warehouses and ship pharmaceutical goods. They provide a wide array of supporting services that enable the pharmaceutical supply chain to function efficiently and safely, delivering significant value to manufacturers and healthcare providers — and ultimately for patients and consumers as well.”²⁷²

The HDA Research Foundation (previously the Center for Healthcare Supply Chain Research - CHCSCR) is a non-profit charitable foundation that serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues, including the development of the HDMA Factbook; The Role of the Distributors in the U.S. Healthcare Industry, among other reports and documents.

Specific responsibilities the HDA performed included:

- coordinating an industry’s response to government concerns and possible legislation
- coordinating and managing strategic communication and advocacy professionals to work on behalf of the industry to ensure favorable publicity
- managing crisis communication
- establishing strategic priorities and launching pro-industry initiatives

In addition, the HDA funded other pro-industry front groups such as the American Pain Foundation.

The Evidence that documents the role of the HDA in these indirect forms of marketing are summarized in Schedule 5.5 (e).

From 2012 through 2017, the HDA was regularly involved with drug abuse discussions and related public relations initiatives, detailed in a 17-page timeline.²⁷³

Role with Government Relations. In 2012, the HDA’s largest budget expenses included staff (\$6.47 million) and outside lobbyists and political consultants (\$1.35 million).²⁷⁴

The minutes from its various Executive Committee meetings over the years communicate its role in the massaging and mitigating governmental concerns regarding the opioid crisis, including ensuring that all Members of Congress (House and Senate) were familiar with the HDMA and its “priority issues,” including opposition of proposed legislation regarding Medicare Part D/Non-Interference Clause²⁷⁵ and regulation regarding brand/generic legislation. They also offered educational programs to Senate Finance committee and industry attorneys, and conducted advocacy work with federal representatives and Hill briefings.²⁷⁶

The HDMA also coordinated the Distributors’ participation in developing the “Industry Compliance Guidelines (ICG): Reporting Suspicious Orders and Preventing Diversion of Controlled Substances”

²⁷¹ [https://www.hda.org/news/2016-06-13-hdma-launches-new-identity-as-hda#:~:text=The%20Healthcare%20Distributors%20Association%20\(HDA\)%20has,industry%20and%20patients%20around%20the%20country.](https://www.hda.org/news/2016-06-13-hdma-launches-new-identity-as-hda#:~:text=The%20Healthcare%20Distributors%20Association%20(HDA)%20has,industry%20and%20patients%20around%20the%20country.), accessed July 18, 2020.

²⁷² <https://www.hda.org/about/hda-history>

²⁷³ ABDCMDL00374353

²⁷⁴ ML00055624

²⁷⁵ HDA_MDL_000159563

²⁷⁶ HDA_MDL_000159198

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including developing thresholds for identifying orders of interest,²⁷⁷ the need for a press release, what should be said/done and to whom,” outreach with members of Congress, and other steps to create the impression that Distributors were onboard with the ICG,²⁷⁸ as well as the Distributors’ preferred wording of a letter to the “ONDCP” (Office of National Drug Control Policy).²⁷⁹

The HDMA circulated questions for the DEA to its members for a discussion on July 31, 2013. The edits provided by Cardinal Health indicate not wanting to antagonize DEA or leave themselves open to unwanted interrogation.²⁸⁰

The HDMA (in conjunction with the National Association of Chain Drug Stores) filed an Amici Curiae to the US Court of Appeals for the District of Columbia Circuit in the Masters Pharmaceuticals v. US DEA case regarding whether the reporting obligations the DEA required was impractical for distributors.²⁸¹ The brief states that distributors do not have the data that would allow them to determine how much of a given drug or product each distributor is selling to a given pharmacy and identifies other problematic issues from their perspective.

Given that the Distributors had a specific agenda to cultivate legislation that worked in their favor, they relied on the HDMA to be present at meetings where it would have been unseemly or problematic for individual company personnel themselves to be present. Internal emails request an HDA executive attend a meeting/brainstorming session to determine if there is anything to do from a public policy perspective to “better educate, or impact Washington policy makers’ thinking with respect to litigation brought by plaintiff’s lawyers and states, cities, counties and municipalities against the opioid supply chain.”²⁸² The email states it would be better to have HDA at meeting rather than individual companies; the HDA executive replies that he would be happy to participate on behalf of the Distributors.

Strategic Communications and Industry Advocacy Work with Government & Media. The HDMA engaged of communications and advocacy professionals. For example, Eric Dezenhall (labeled the “pitbull of public relations”)²⁸³ and David Winston (Winston Group) presented research results and a situational assessment regarding public perceptions of the role of distributors, manufacturers, and pharmacies.²⁸⁴ Recall from Section II that a situational assessment is the systematic process used to provide the foundation for a marketing strategy.

The HDA realized the importance of public relations to its members in allowing them to continue to generate and benefit from the ever-increasing opioid demand. The budget for the HDA public relations campaign for the years 2018 – 2020, totaled \$9.5 million dollars, with the “assessment charge per company” divided equally between ABC, CAH, and MCK in 2020.²⁸⁵

²⁷⁷ ABDCMDL00000397; HDA_MDL_000081671

²⁷⁸ HDA_MDL_000081669

²⁷⁹ PPLP004210521

²⁸⁰ CAH_MDL2804_03250329

²⁸¹ HDA_MDL_000162207

²⁸² PPLPC020001151103

²⁸³ <https://www.propublica.org/article/inside-purdue-pharma-media-playbook-how-it-planted-the-opioid-anti-story>

²⁸⁴ HDA_MDL_000159563

²⁸⁵ MCKMDL00719205

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Mr. Dezenhall concluded that the HDMA and the primary distributors' brand needed strengthening to establish credibility, without which it is a target for attack.²⁸⁶ His company was retained by the HDMA to do this work. The work included:²⁸⁷

- Enhancing Day-to-Day Communications Operations and Engagement: how to manage media inquiries, updating the government affairs/industry relations sections of the website; developing key communications materials for priority issues; updating media distribution lists and updating the list of external experts for the media; spokesperson training, and updating the HDMA boilerplate presentation;
- Systematic Upgrades to Communications Tools and Resources: building a better website; upgrading the Weekly Digest for HDMA members;
- Ongoing Stakeholder Engagement: building relationships and communication channels before you need them with the Public Affairs Council, the trade media - listed by name here- and other association engagement;
- Strategic Communications: advocacy for reimbursement, pedigree, drug diversion, REMS, and generics; this would include government affairs planning and brainstorming for publications from the Center for Healthcare Supply Chain Research (the HDMA's non-profit research arm); and
- Advanced Engagement, including a full-time VP of communications for more proactive media outreach; lengthier feature article pitches, speaking opportunities, white papers/research reports, etc.

This comprehensive strategy that Dezenhall's firm provided for the HDMA speaks to the sophistication approach the Distributors collectively benefited from with respect to strategic communications.

In addition, the HDMA hired the prestigious consultancy Booz Allen Hamilton to "refresh" the Industry Value Proposition Study.²⁸⁸

Managing Crisis Communications. Recall from Section II that public relations includes not just attempting to influence media coverage so it portrays a company and its products in the most favorable light possible; it also includes crisis communications—e.g., proactively preparing for how to respond to situations when a company and/or its products have caused harm in some way.

The HDMA had a "Crisis Playbook," developed in conjunction with yet another advisory and advocacy communications consultancy, APCO.²⁸⁹ This detailed Crisis Playbook offers guiding principles for crisis communication/reporting, including a crisis classification system and scenario planning based on level of risk and likelihood of occurrence; a communications approach (proactive media outreach, responsive media outreach, or none); stakeholder considerations; and other details. The specific application of how to effectively use the Playbook appears with about 10 specific scenarios/case studies, including DEA Registration Suspension of an HDMA Member/distribution center; a Diversion Lawsuit; Congressional Inquiry, among others.

In addition, the HDMA engaged gmb, a DC-based communications firm to develop a "Strategy to Turn the Tide in West Virginia" (referencing "the tide of imbalanced media coverage and public perception

²⁸⁶ HDA_MDL_000159563

²⁸⁷ HDA_MDL_000202605

²⁸⁸ HDA_MDL_000159557

²⁸⁹ ABDCMDL00288484

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about the healthcare distributors' role in painkiller abuse").²⁹⁰ The memo states that if steps are not taken, the HDMA and its members risk negative impacts, including "possible disruption to passage of Senate Bill 483."²⁹¹ Among the recommendations are hosting a summit to preempt S. 483 to position HDMA as a leader and frame companies as part of the solution. Other steps to "turn the tide" include specific identification of target audiences (including West Virginia media, national media, law enforcement, politicians, third parties); key messages to use and a specific timetable for six months of outreach to implement the plan.

AmerisourceBergen was pleased with a change in tone in press coverage. The HDA had been contacted by a reporter and was able to influence the final story. The ABC's email states, "Charlie (Charles Ornstein the ProPublica writer) is the first reporter to actually use the information we provided."²⁹²

An email thread between AmerisourceBergen, Cardinal Health, and McKesson discussed a proposed "to let HDA take the lead" regarding proactive preparation in response to fallout from the upcoming 60 Minutes and WAPO (presumably Washington Post) stories.²⁹³ Because companies can express their own point of view in their own social media, the email states the goal to use social media to "broadcast our point of view" by using LinkedIn (to reach professionals that may have a stake in pending litigation) and behavioral targeting on Facebook to reach those who may have actually seen the 60 Minutes episode.²⁹⁴ The media impressions achieved could be precisely measured. Cardinal Health also had an internal memo with talking points for employees about how to respond to the fall-out from this negative press.²⁹⁵

Similarly, AmerisourceBergen expressed concern regarding a letter "the Post" published and how the HDA could best respond to this. The memo references a DC crisis firm the HDA engaged, Reservoir. ABC wanted the HDA to "say the things we can't/won't."²⁹⁶

Industry Front Groups' Role in Media and Government Relations.

Both the Pain Care Forum and the American Pain Foundation are examples of industry front groups, and the HDMA was a participating organization in the Pain Care Forum.²⁹⁷

As might be expected, these industry front groups used the same marketing tactics as the HDA—media/public relations strategies and government relations—to curry favor with politicians and reporters to ensure favorable treatment so they could continue to grow and benefit from opioid sales.

The **American Pain Foundation** used sophisticated efforts in securing media coverage and engaging in government lobbying.²⁹⁸ Its 2010 annual report included an overview of its "educational activities" and political lobbying, and its engagement in media interviews, as well as efforts to secure favorable media

²⁹⁰ ABDCMDL00269293; ABDCMDL00269301

²⁹¹ *Id.*

²⁹² ABDCMDL03829334

²⁹³ ABDCMDL03830243

²⁹⁴ *Id.*

²⁹⁵ CAH_MDL2804_00112004

²⁹⁶ ABDCMDL00375084

²⁹⁷ ABDCMDL00264245

²⁹⁸ ENDO-OPIOID_MDL-00394248

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coverage.²⁹⁹ The APF's communication to its members³⁰⁰ details the unbalanced and unfair media coverage perpetuating misinformation about prescription pain meds and encourages members to take action by insisting these news outlets act responsibly and demand balanced reporting (specific ideas are listed in the email).³⁰¹

Moreover, the American Pain Foundation used the same communications and advocacy firm as the HDA, Dezenhall, to secure favorable media coverage by training spokespeople to speak to the media and preparing advocates for testimony before Congress.³⁰² Dezenhall highlights its success in cultivating favorable media influence for its prior work, including:³⁰³

- its preparation of a “virtual textbook” made free to medical schools across the U.S. for the American Academy of Pain Medicine.
- a booth on behalf of the National Pain Foundation at a national conference for pain physicians where each could record a 30-second public service announcement (PSA) about the plight of pain patients and the need for appropriate pain therapy; Dezenhall then taught physicians how to approach local radio stations to get these PSAs aired.
- its work with Purdue Pharma’s Law Enforcement Liaison and Education (LELE division) to secure media coverage in critical markets with over 5.6 million readers/viewers reached.

As with its work for the HDA, Dezenhall performed tasks for the APF including media list development, advocate identification, development of pitches to media, follow-up calls, and media monitoring for 25 markets.³⁰⁴

Its work accomplished the objective of influencing media coverage to be favorable to the use of opioids. Dezenhall documents “success in fighting negative coverage” from July 2001 through 2006, with a list of about 15 articles that they influenced.³⁰⁵ In addition, an article in the Dallas Morning News featured pain advocate Fran Di Giacomo, part of Dezenhall’s media campaign to support APF’s HR 1020 legislation.³⁰⁶ In addition to the article mentioned, 12 companion articles ran in the feature on pain management, and the reporter included a link to the APF website in the stories as well as information on HR 1020.³⁰⁷

Dezenhall also coordinated events such as a Washington state event for the Washington Pain Forum. The press release for the event noted that “Physicians are experiencing pressures that drive them to under-treat pain and are driving them away from people with pain.”³⁰⁸

In its attempts to cultivate favorable media coverage, the American Pain Foundation also prepared a thorough Reporter’s Guide: “Covering Pain and its Management,” to provide a “useful resource for busy reporters, provide information to editors and producers covering pain stories.”³⁰⁹ The Guide includes

²⁹⁹ ENDO-OPIOID_MDL-01623042

³⁰⁰ ENDO-OPIOID_MDL-02217039

³⁰¹ *Id.*

³⁰² CHI_000272862

³⁰³ *Id.*

³⁰⁴ *Id.*

³⁰⁵ PPLPC029000177585

³⁰⁶ PPLPC031000385886

³⁰⁷ *Id.*

³⁰⁸ PKY183402315

³⁰⁹ JAN-MS-04241287

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using the APF to connect reporters to experts for interviews; provides pain statistics and facts; includes “Special Topic Briefs” on pain in specific populations, chronic pain and opioid therapy; and provides a glossary of common pain terms and syndromes. The basic goal is to convey the message that pain is undertreated due to misconceptions about opioid addictions and physician fears of scrutiny.

Each of these efforts by the APF shows a sophisticated approach to elevating the opioid market to the benefit of all supply chain participants. Given the HDA’s support of the APF, the Distributors are implicated in these activities.

Recall from Section III, Basic Duties of Marketers, industry trade associations “that appear independent but are actually funded and influenced by companies with a vested interest”³¹⁰ are violations of the Code of Ethics for Public Relations professionals. Moreover, recruiting individuals to participate in media campaigns that are conveyed as grass roots (authentic) is also improper.³¹¹

D. Financial Rewards from the Integrated Efforts of Distributors’ Marketing for Opioids³¹²

Both the opioid manufacturers and the Distributors benefited financially from the coordinated approach to marketing opioids. Recall from Section IV that a key benefit of an integrated supply chain is increased demand and thus increased sales and profitability.

1. Distributors’ Marketing Activities Generated ROI for Opioid Manufacturers³¹³

The marketing activities that the Distributors performed for the opioid manufacturers were highly effective. The Distributors provided solid evidence of the return-on-investment (ROI) of their marketing services provided to the manufacturers, showing that their efforts increased demand for opioids.

McKesson’s RelayHealth Program showed results that included: 173% NRx (new prescription) lift for newly launched products; a 27% improvement in patient adherence; 90% sustained lift after 12 months; for an ROI of 4:1. These results lead McKesson to claim this program offers manufacturers a “flexible, efficient engine to maximize investment in core marketing tactics.”³¹⁴

A similar program using McKesson’s evouchers (electronic savings cards) and paying pharmacists for participation documented that a majority of patients who received the evoucher switched from a competitor’s product. Those patients who received the evoucher were “top performers” over a control group of patients (who didn’t receive the offer). The program also increased the number of New to Oxycontin patients who filled a second script sooner (39% for program vs. 26% for a control group of customers who didn’t receive the offer), leading to an estimated ROI = 15%. Finally, the data provided also show a change in physician prescribing behavior leading to a halo effect of .8% in sales lift.³¹⁵

³¹⁰ <https://www.prsa.org/about/ethics/prsa-code-of-ethics>

³¹¹ *Id.*

³¹² See Schedule 5.D

³¹³ Evidence for this section can be found in Schedule 5 D (1).

³¹⁴ PPLPC030000564197

³¹⁵ PPLPC025000149099

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McKesson's documented evidence for its RelayHealth Pharmacy Solutions for Actavis/Allergan showed a demonstrated 2.4x enhancement in patient affordability on prescriptions and a 137% ROI on its "eVoucherRx" coupons for co-pay assistance.³¹⁶

The Distributors had the data to prove that their marketing services increased demand and benefited all parties in the integrated supply chain.

2. Distributors Benefited from Sales Lift from their Marketing Services.³¹⁷

The compensation the manufacturers paid to the Distributors for these marketing services (e.g., beyond the mark-up Distributors made for distributing products to pharmacists) included both fee-for-service arrangements as well as bonuses based on sales lift attributed to the marketing the Distributors performed on behalf of the manufacturers. For the Distributors to claim that they were not compensated for sales lift is false.

Recall from Section IV that channel alignment is optimized when manufacturer's use compensation to align the Distributors' interests with its own. In this case, the pharmaceutical manufacturers ensured the Distributors were incentivized financially to grow sales over time.

Mallinckrodt paid McKesson a [REDACTED] marketing allowance for its Onestop Generics Program "if McKesson awards a primary position to its morphine products," and it also specified an additional volume rebate: from April 1, 2007 through March 31, 2008 "McKesson will be eligible for various volume rebate percentages" ranging from a low of 11% if McKesson's yearly dollar volume is [REDACTED] to a high of 20% if McKesson's yearly volume is greater than \$80MM.³¹⁸

Similarly, Mallinckrodt offered McKesson a one-time Marketing Allowance of [REDACTED] if McKesson awards Fentanyl Lozenge products a primary position and submits an order totaling [REDACTED], and McKesson will also be eligible for the 20% volume rebate dated June 2, 2008.³¹⁹

In its request to McKesson to promote Actavis as the alternate vendor for the fentanyl patch to participating members of McKesson OneStop Generic Source Program (from April 1, 2009 through March 31, 2010) with discount pricing, Actavis' contract stated the profits from the promotion would be "split between the two parties 50/50 through Nov. 1, then McKesson gets 30% thereafter."³²⁰

Mallinckrodt's Covidien Specialty Generics group offered ABC "payout" (rebate) tiers on Fentanyl and encouraged them to bump Fentanyl to a primary position in order to lock in a higher rebate value to 18-20%. Movements that "could pay off in a big way for ABC."³²¹

³¹⁶ MCKMDL00724422

³¹⁷ See Schedule 5 D.2.

³¹⁸ MNK-T1_0006684264

³¹⁹ MNK-T1_0000416504

³²⁰ Acquired_Actavis_00669723

³²¹ MAL-MI 000240890 / MNK-T1_0000499742

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Mallinckrodt's contract with Amerisource Bergen for its PrxO Generics agreement was amended to change the rebate percentage; the new percentages would range from a low of a 13% rebate for \$80-90M in volume, and a high of 18% for \$150M or more.³²²

Mallinckrodt compensated ABC's Global Services (GmbH) marketing group both with a fee for service, plus an "*enhanced marketing fee*" where the manufacturer shall pay ABC .25% of the contract price based on incremental sales for each Fentanyl product using a three-month average of sales from March, April, May 2016 as the base compared to the promotional period of August 1-30, 2016.³²³ This enhanced marketing fee was also offered on its December 16, 2016 contract, for incremental sales for each Fentanyl product using the three-month average sales from Sept, Oct, Nov 2016 as the base compared to the promotional period of January 1-March 31, 2017.³²⁴

VII. CONCLUSION

In conclusion, the Distributors worked in an integrated, closely aligned supply chain to sell prescription opioids. Based on their central role in connecting the opioid manufacturers to pharmacists, healthcare providers, and other downstream entities, the Distributors took an active part in growing the demand for prescription opioids through the various marketing techniques they provided to the opioid manufacturers. Distributors were financially incentivized and worked with opioid manufacturers to expand the market for opioids and sell more opioid drugs. The techniques the Distributors used are highly sophisticated in their reliance on data and technology to grow demand and to track the effectiveness of their marketing efforts.

³²² MAL-MI 000241028 / MNK-T1_0000499880

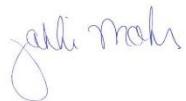
³²³ ABC-MSAGC00002141; ABDCMDL00002141

³²⁴ ABDC-JNAG00000372; ABDCMDL00002632

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Pursuant to 28 U.S.C. S 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 1, 2020.



Jakki J. Mohr, Ph.D